Phonetic and Orthographic Computer Analysis (POCA)

Installation Guide

Version 4.3
October, 2019

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NOTICE

The FDA is unable to provide technical support for this software and does not plan to release future versions. If you have any comments on this software please email pocasourcecoderequest@fda.hhs.gov.

1. SYSTEM REQUIREMENTS

There are two options available for deploying the database and the application for POCA in Public Release.

Option #1 (Two Tier System):

The database can be deployed on to one tier and the application can be deployed to the company's intranet web server (second tier). It is recommended that this deployment option should be performed by the experienced Oracle DBAs and server administrators. The database can be deployed on Windows, UNIX, or Linux Operating Systems. The recommended version of Oracle Database is 12c . The application must be deployed on a Windows application server. The minimum requirements recommended for the Windows application server are:

a. Windows 2012, Windows 2008, Windows 7, Windows 8, Or Windows 10
b. IIS 6/7/8
c. Oracle 11g/12c Client (including ODP.Net)
d. Microsoft .Net Framework 4.0
e. 8 GB RAM
f. 4 GB Disk space available
g. Visual Studio 2010 (only needed if modification to the source code is required)

Option #2 (Single Tier System):

The database and application can be deployed on one Windows server or PC. The minimum requirements recommended for this configuration are:

a. Windows 2012, Windows 2008, Windows 7, Windows 8, Or Windows 10
b. IIS 6/7/8
c. Oracle 12c R1 Database
d. Microsoft .Net Framework 4.0
e. 8 GB RAM
f. 20 GB Disk space available
g. Visual Studio 2010 (only needed if modification to the source code is required)

OPTION #1 IS BEST DEPLOYED BY EXPERIENCED DBAs AND SERVER ADMINISTRATORS.

Information will be provided for both the options. However, to accommodate users not familiar with installing Oracle, some example screen prints and details will be provided for Option #2.

Download Software from FDA internet site: Download the zip file from the FDA internet site to your local computer (preferably in C: drive). Unzip or extract the software to your local drive. The extracted files will be used to install, configure, and setup both the database and the POCA application. The generic name of the unzipped folder is 'POCA Installation Folder'.

There are **two paths** to get to the latest version of the POCA application. If you already have the POCA **Version 4.2** running either in Two-Tier or Single-Tier, you can simply apply the upgrade script and copy the latest software. In all other cases and if you want to follow the full install despite having an earlier version, follow the full install path steps.

2. UPGRADE PATH

If you are already working on a prior version POCA 4.2, please follow the instructions below.

2.1 Download POCA Software from FDA internet site

Download the zip file from the FDA internet site to your local computer (preferably in C: drive). Unzip or extract the software to your local drive. The extracted files will be used to install, configure, and setup both the database and the POCA application. The generic name of the unzipped folder is 'POCA Installation Folder'.

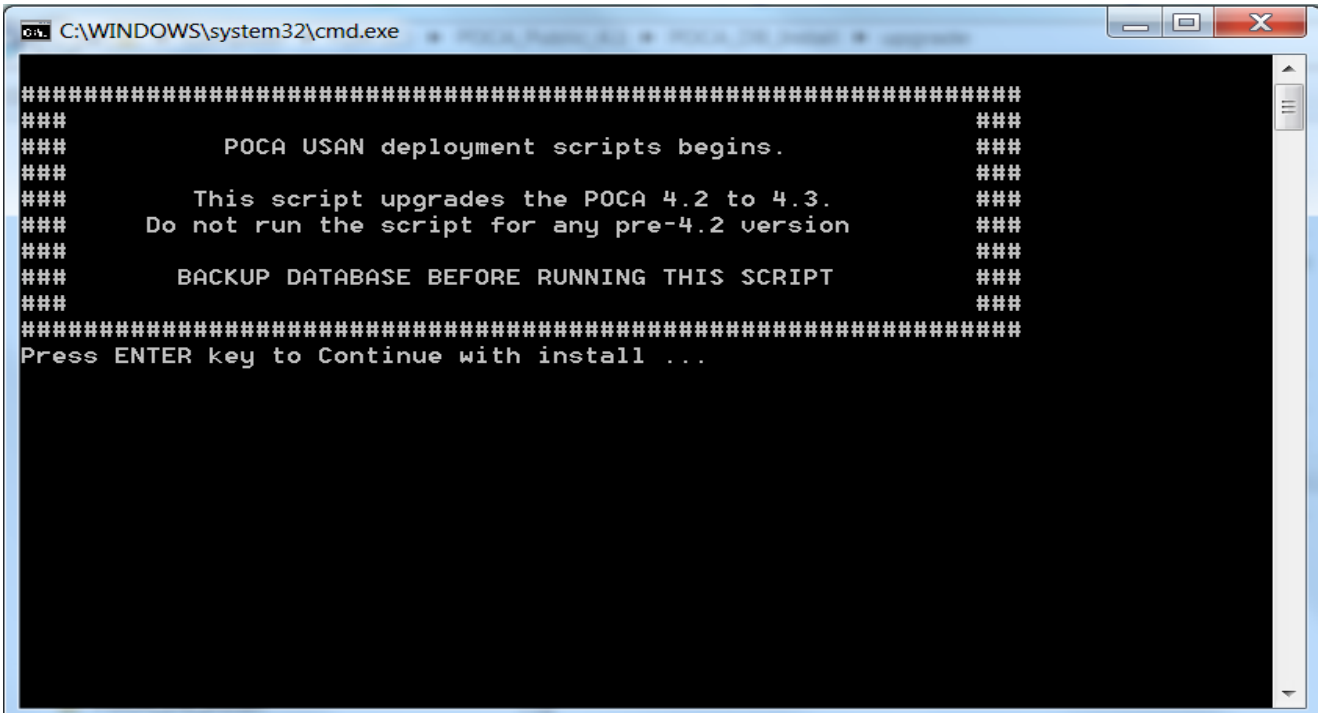
This deployment option is recommended for experienced DBAs and server administrators. It is assumed that a mail server is already configured and accessible.

1. Keep ready the credentials for the current POCA user and database for the existing Oracle 12c R1 database.
2. Download the compressed (zip) file provided in the FDA web site and unzip the file.
3. Copy the POCA_DB_Install directory from the unzipped folders to the C: drive on the server or an appropriate temporary directory on a Unix/Linux server. This directory can be deleted when the installation is complete.

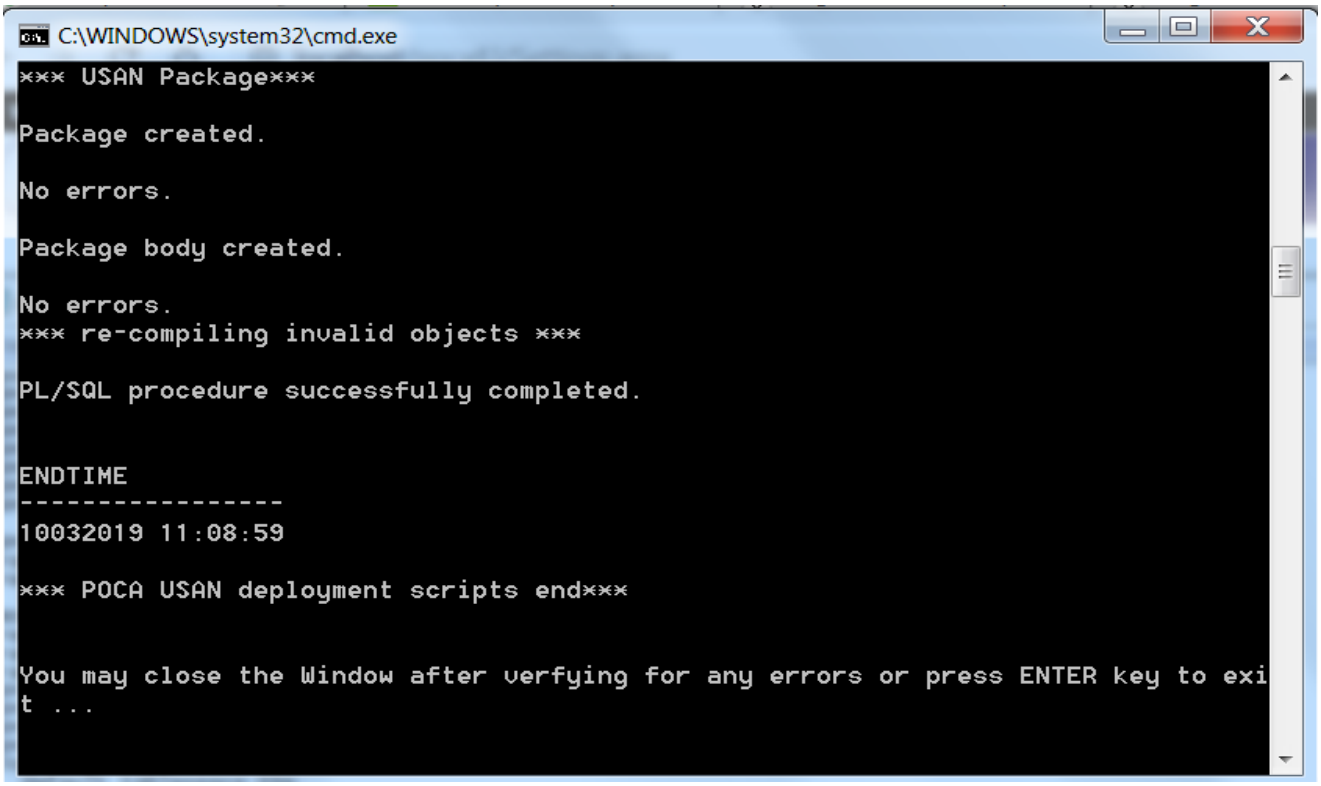
2.2 Run Upgrade script

Locate the upgrade_42_43_poca.bat or upgrade_42_43_poca.sh in the folder POCA_DB_Install\upgrade depending on where you are running the script from. Follow the prompts and if the database backup is already available, provide the sys user password when prompted. If your database connect string is different from poca, edit the script with correct information before running.

If you encounter any issues with running the batch or Shell script, login as sys from sqlplus manually and run the script poca_usan_43_deploy_scripts.sql from the folder POCA_DB_Install\upgrade.



When the script completes, you can check the logs on the screen and press enter.



Next Step would be updating the application.

2.3 Upgrade the application from 4.2

Assumptions:

- C:\Inetpub\wwwroot is the default folder for IIS virtual directories
- .Net framework 4.0 is installed
- POCA 4.2 application is already running.

Locate the folder 'poca' under C:\Inetpub\wwwroot. On the POCA extracted folder, find the folder "POCA_Published_Files."

Backup the POCA 4.2 code including Web.config if you made any specific changes with the old version.

Copy the contents of the folder into the x:\Inetpub\wwwroot\poca folder on your computer, where x is the drive where IIS is installed (usually C:\).

Restore the Web.config if it was backed up as part of the install.

Recycle IIS and test the application.

Open the URL http://poca.pub.com/ and Log into the application with the User ID "Admin" and password "pocaadmin$"

NOTE: If you have issue installing the application please refer to Section 4 in this document.

3. Full Install Path (Database)

3.1 Option #1

Download the zip file of POCA software and other documents from the FDA internet site to your local computer (preferably in C: drive). Unzip or extract the software to your local drive. The extracted files will be used to install, configure, and setup both the database and the POCA application. The generic name of the unzipped folder is 'POCA Installation Folder'.

This deployment option is recommended for experienced DBAs and server administrators. It is assumed that a mail server is already configured and accessible.

1. Install Oracle 12c R1 database software on a database server or if already installed use an existing Oracle 12c R1 database.
2. Download the compressed (zip) file provided in the FDA web site and unzip the file.
3. Copy the POCA_DB_Install directory from the unzipped folders to the C: drive on the server or an appropriate temporary directory on a Unix/Linux server. This directory can be deleted when the installation is complete.
4. Open the script 'create_POCA.sql' available in the directory 'POCA_DB_Install\full'. If deploying on Unix or Linux, the Windows pathnames (highlighted below) need to be changed with "/". For your reference the section '**C:\app\oracleHomeUser1\oradata\POCA**' needs to be modified based on Oracle Home, Oracle Base, Datafile location and Database configuration based on the existing system. This will be the location of data file for the POCA schema.

create_poca.sql - Notepad

File Edit Format View Help

```
spool C:\POCA_DB_Install\cr_POCA.log
REM ******************************************************
REM All references to directories will need to be changed
REM to match the directory structure of the server
REM
REM *** RUN THIS SCRIPT AS SYS USER ***
REM
REM ******************************************************

REM Create FDA tablespaces
drop tablespace FDA including contents and datafiles;
create tablespace FDA
   datafile 'C:\app\oracleHomeUser1\oradata\POCA\poca_data.dbf' size 2000M REUSE AUTOEXTEND ON MAXSIZE 3000M;
DROP USER POCA CASCADE;
create user poca identified by poca_user;
grant create session to poca ;
grant dba to poca ;
REM ***************************************
REM * set default tablespace and
REM * temporary tablespace for user poca.
REM ***************************************
alter user poca
   default tablespace FDA
   temporary tablespace temp
   quota unlimited on FDA;
grant execute on sys.dbms_session to poca;
grant execute on sys.dbms_sql to poca;
grant execute on sys.dbms_output to poca;
grant execute on sys.dbms_job to poca;
grant select on sys.dba_users to poca;
grant select on sys.dba_jobs to poca;
grant select on sys.dba_views to poca;

REM
REM Create pocaadmin role and grant permissions to this role
REM
/*
create role pocaadmin identified by pocaadmin;
```

NOTE: If you encounter ORA-65096 error, please refer to the section 5: Additional Notes

5. Create a physical folder 'dump_dir' in the server (e.g. in C: drive) where Oracle database is installed. Change the path names as appropriate for Unix/Linux. Place the dump file 'pocapub.dmp' from 'C:\POCA_DB_Install\full' to the dump_dir directory.

6. Create a folder C:\poca_data_import in the server where Oracle database installed. Please change the path as appropriate to Unix/Linux.

7. Go to C:\POCA_DB_Install\full folder and execute by double-clicking the batch file 'import_poca.bat'. Or for Unix 'sh import_poca.sh'.

   NOTE: Provide poca/poca_user@poca if you have not changed from default or give correct password and connect strings changed them
   OR
   Execute the data dump import command as follows. Run from the command prompt

(change username/password and connect string as needed).

```
impdp poca/poca_user@poca DIRECTORY=dump_dir dumpfile='pocapub.dmp'
logfile='imp_poca.log' schemas=POCA
```

Data load and post-import setup

8. The POCA database includes four data sources: DrugsatFDA, RxNorm, Suffixes in proper name of biological products and USAN which will upload upon installation. To upload monthly data refreshes for these data sources, follow the instructions 9 through 10 below.

9. Connect SQL*Plus as the POCA user and run the following SQL update command. This is necessary for you to provide the value of the full directory path of the 'POCA_DATA_IMPORT'. As an example 'C:\POCA_DATA_IMPORT' for windows and '/POCA_DATA_IMPORT' for UNIX OS.

```
SQL>UPDATE POCA.USER_SETTING SET U_SETTING_VALUE = 'C:\POCA_DATA_IMPORT'
WHERE I_SETTING_ID = 4084 AND UI_USER_UID = '01';
COMMIT;

SQL> Truncate table POCA.USER_PASSWORD_HISTORY;

SQL> UPDATE "POCA"."USERS" SET DT_LAST_LOGON =sysdate, I_LOGON_COUNT = '0',
DT_CREATED =sysdate, DT_UPDATED =
sysdate,i_failed_attempts=0,f_password_expired=0 WHERE U_USERNAME='Admin';

SQL>COMMIT;
```

10. For future drugs data, FDA will provide formatted data files in the internet site. You can download data files from there and copy those into 'poca_data_import' directory and The format of the data file names would be as 'rxnorm_YYYYMMDD _New.txt' for RxNorm data file and 'drugsatfda_YYYYMMDD_New.txt for DrugsatFDA data file (Example for YYYYMMDD is 20160922 for Sep 22, 2016 is the download date) and similar formats for USAN and Suffix data. After that you can load data through POCA application. Details of data load procedures are described in Help manual.

Email Settings (OPTIONAL)

11. In order to implement the email functionalities of the POCA application to work, some email settings in the database need to be changed. It is necessary to edit and run three scripts and run one update command as follows. **THIS IS REQUIRED IF YOU HAVE ANY SMTP EMAIL SERVER**. If not just skip this step.

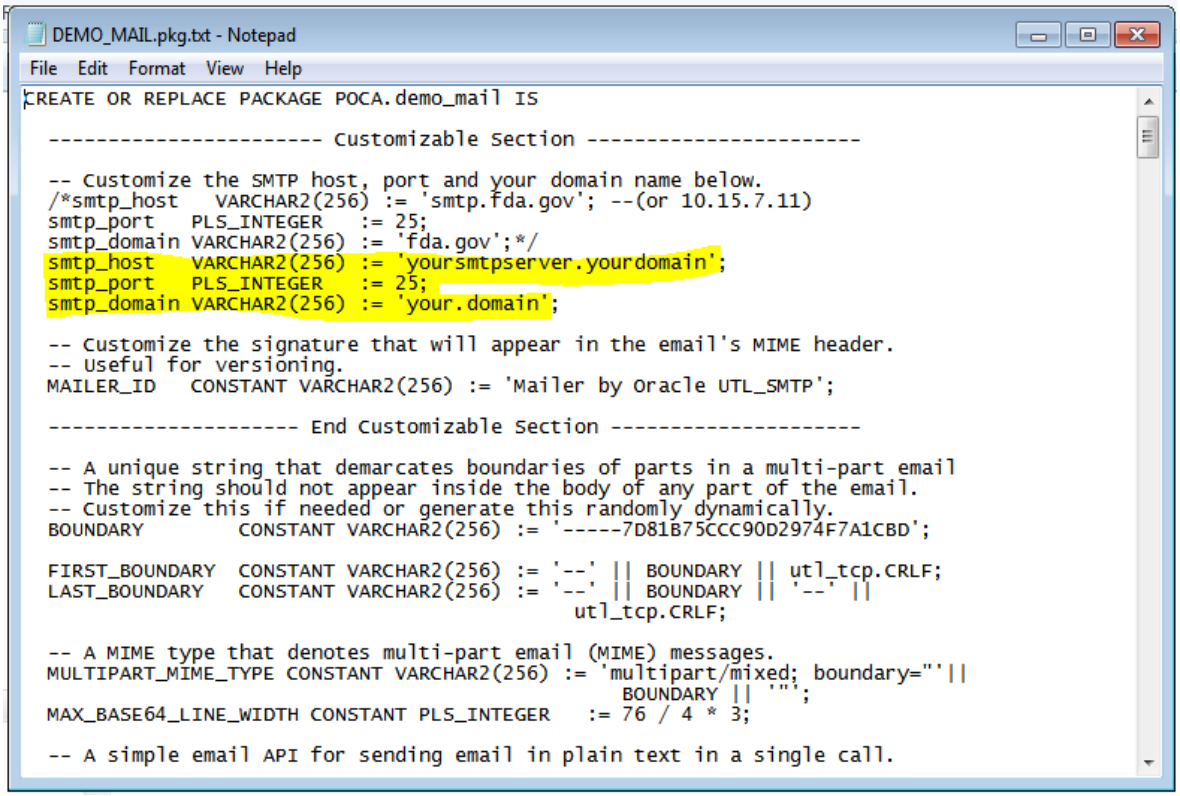
    a. In the C:\POCA_DB_Install\full directory, open the file demo_mail_pkg.sql in Notepad. At the top of the file you will find a section labelled "Customizable Section" as shown below. Change the smtp_host, smtp_port (if necessary), and smtp_domain to the correct values as applicable to your company's email.

Save the file.

---------- Customizable Section ----------

-- Customize the SMTP host, port and your domain name below.
smtp_host VARCHAR2(256) := 'yoursmtpserver.yourdomain';
smtp_port PLS_INTEGER := 25;
smtp_domain VARCHAR2(256) := 'your.domain';

-- Customize the signature that will appear in the email's MIME header.
-- Useful for versioning.
MAILER_ID CONSTANT VARCHAR2(256) := 'Mailer by Oracle UTL_SMTP';



---------- End Customizable Section ----------

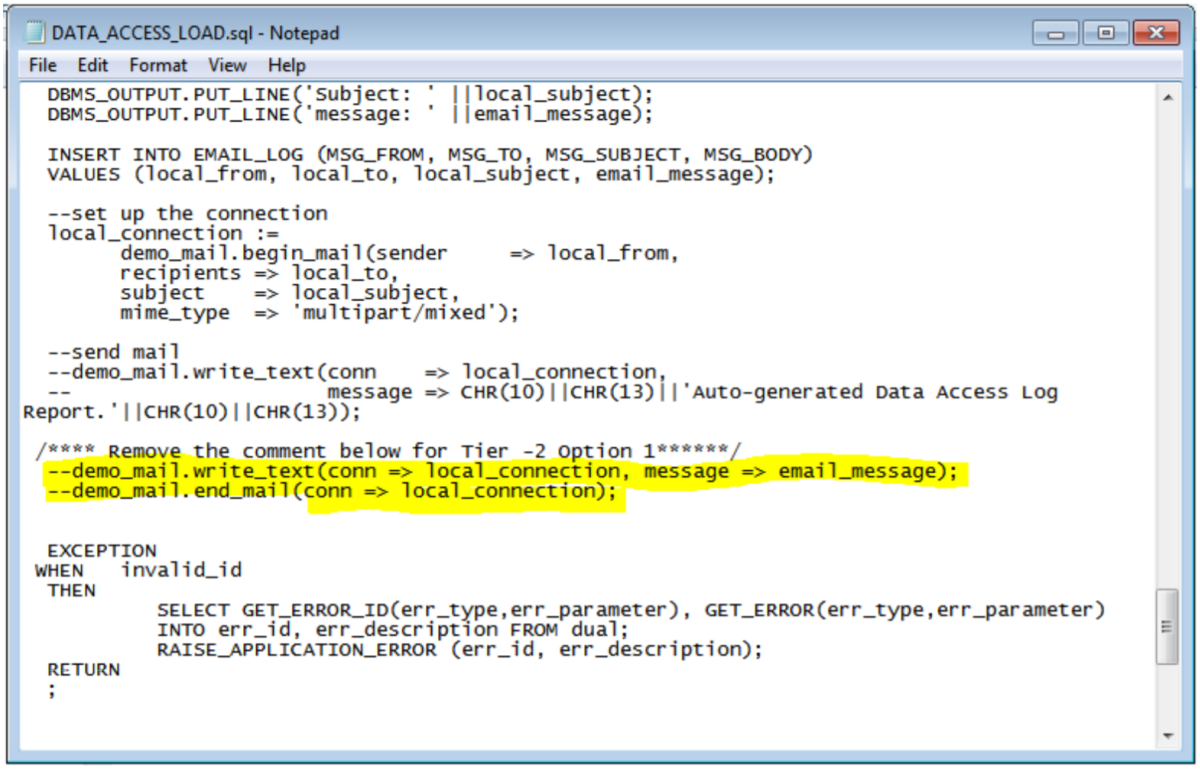
b. In the C:\POCA_DB_Install\full directory you will find DATA_ACCESS_LOAD.sql, open the file in a Notepad. Find the section labeled "/* SEND EMAIL */." Enter your desired email address in the single quotes where it says youremail@domain. Save the file.

DATA_ACCESS_LOAD.sql - Notepad

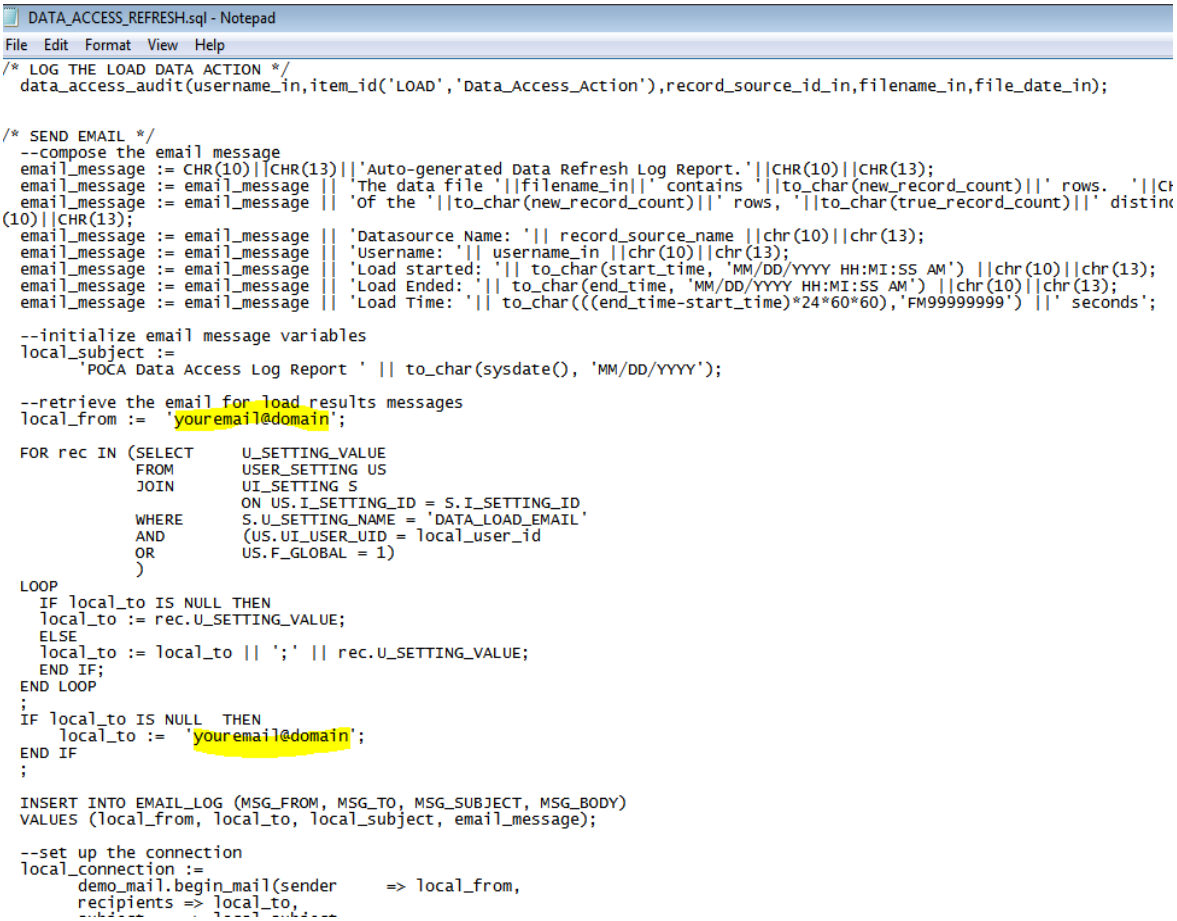
File Edit Format View Help

```
(10)||CHR(13);
  email_message := email_message || 'Datasource Name: '|| record_source_name ||chr(10)||chr(13);
  email_message := email_message || 'Username: '|| username_in ||chr(10)||chr(13);
  email_message := email_message || 'Load started: '|| to_char(start_time, 'MM/DD/YYYY HH:MI:SS AM') ||chr(10)||chr(13);
  email_message := email_message || 'Load Ended: '|| to_char(end_time, 'MM/DD/YYYY HH:MI:SS AM') ||chr(10)||chr(13);
  email_message := email_message || 'Load Time: '|| to_char(((end_time-start_time)*24*60*60),'FM99999999') ||' seconds';

  --initialize email message variables
  local_subject :=
        'POCA Data Access Log Report ' || to_char(sysdate(), 'MM/DD/YYYY');


  --retrieve the email for load results messages
  local_from :=  'youremail@domain';

  FOR rec IN (SELECT     U_SETTING_VALUE
              FROM       USER_SETTING US
              JOIN       UI_SETTING S
                         ON US.I_SETTING_ID = S.I_SETTING_ID
              WHERE      S.U_SETTING_NAME = 'DATA_LOAD_EMAIL'
              AND        (US.UI_USER_UID = local_user_id
              OR         US.F_GLOBAL = 1)
              )
  LOOP
    IF local_to IS NULL THEN
    local_to := rec.U_SETTING_VALUE;
    ELSE
    local_to := local_to || ';' || rec.U_SETTING_VALUE;
    END IF;
  END LOOP
  ;
  IF local_to IS NULL THEN
      local_to :=  'youremail@domain';
  END IF
  ;

  DBMS_OUTPUT.PUT_LINE('From: ' ||local_from);
  DBMS_OUTPUT.PUT_LINE('To: ' ||local_to);
  DBMS_OUTPUT.PUT_LINE('Subject: ' ||local_subject);
  DBMS_OUTPUT.PUT_LINE('message: ' ||email_message);

  INSERT INTO EMAIL_LOG (MSG_FROM, MSG_TO, MSG_SUBJECT, MSG_BODY)
  VALUES (local_from, local_to, local_subject, email_message);

  --set up the connection
  local_connection :=
        demo_mail.begin_mail(sender     => local_from,
        recipients => local_to,
        subject    => local_subject,
```

c. Find the section of the procedure as above where 'demo_mail' is called and uncomment the two lines as highlighted by removing two dashes (--) at the beginning of the lines.

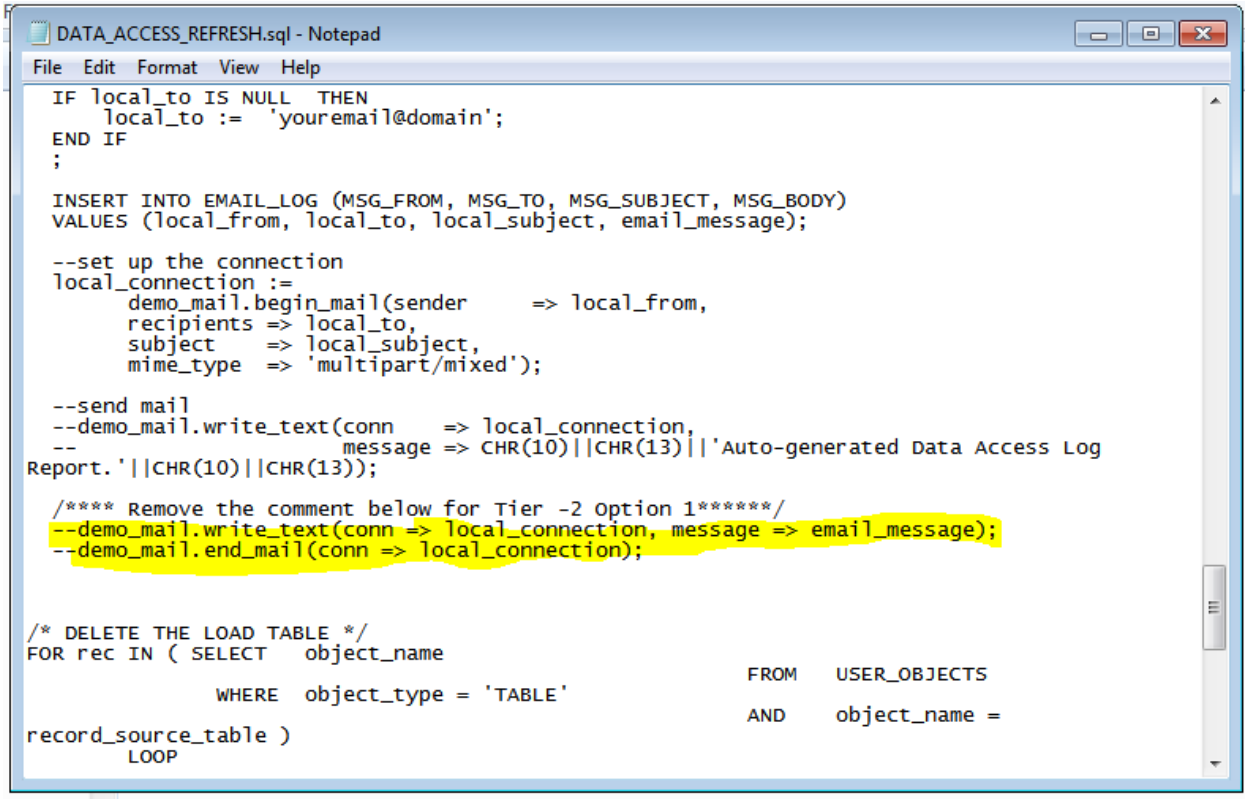

DATA_ACCESS_LOAD.sql - Notepad
File Edit Format View Help
DBMS_OUTPUT.PUT_LINE('Subject: ' ||local_subject);
DBMS_OUTPUT.PUT_LINE('message: ' ||email_message);
INSERT INTO EMAIL_LOG (MSG_FROM, MSG_TO, MSG_SUBJECT, MSG_BODY)
VALUES (local_from, local_to, local_subject, email_message);
--set up the connection
local_connection :=
demo_mail.begin_mail(sender => local_from,
recipients => local_to,
subject => local_subject,
mime_type => 'multipart/mixed');
--send mail
--demo_mail.write_text(conn => local_connection,
-- message => CHR(10)||CHR(13)||'Auto-generated Data Access Log
Report.'||CHR(10)||CHR(13));
/**** Remove the comment below for Tier -2 Option 1******/
--demo_mail.write_text(conn => local_connection, message => email_message);
--demo_mail.end_mail(conn => local_connection);
EXCEPTION
WHEN invalid_id
THEN
SELECT GET_ERROR_ID(err_type,err_parameter), GET_ERROR(err_type,err_parameter)
INTO err_id, err_description FROM dual;
RAISE_APPLICATION_ERROR (err_id, err_description);
RETURN
;

d. Similarly, in the C:\POCA_DB_Install\full directory, open the file DATA_ACCESS_REFRESH.sql in a Notepad. Find the section labeled "/* SEND EMAIL */." Enter your desired email address in the single quotes where it says youremail@domain as highlighted in yellow and save the file.



```
DATA_ACCESS_REFRESH.sql - Notepad
File  Edit  Format  View  Help
/* LOG THE LOAD DATA ACTION */
  data_access_audit(username_in,item_id('LOAD','Data_Access_Action'),record_source_id_in,filename_in,file_date_in);


/* SEND EMAIL */
  --compose the email message
  email_message := CHR(10)||CHR(13)||'Auto-generated Data Refresh Log Report.'||CHR(10)||CHR(13);
  email_message := email_message || 'The data file '||filename_in||' contains '||to_char(new_record_count)||' rows.  '||CH
  email_message := email_message || 'of the '||to_char(new_record_count)||' rows, '||to_char(true_record_count)||' distinc
(10)||CHR(13);
  email_message := email_message || 'Datasource Name: '|| record_source_name ||chr(10)||chr(13);
  email_message := email_message || 'Username: '|| username_in ||chr(10)||chr(13);
  email_message := email_message || 'Load started: '|| to_char(start_time, 'MM/DD/YYYY HH:MI:SS AM') ||chr(10)||chr(13);
  email_message := email_message || 'Load Ended: '|| to_char(end_time, 'MM/DD/YYYY HH:MI:SS AM') ||chr(10)||chr(13);
  email_message := email_message || 'Load Time: '|| to_char(((end_time-start_time)*24*60*60),'FM99999999') ||' seconds';

  --initialize email message variables
  local_subject :=
        'POCA Data Access Log Report ' || to_char(sysdate(), 'MM/DD/YYYY');

  --retrieve the email for load results messages
  local_from :=  'youremail@domain';

  FOR rec IN (SELECT     U_SETTING_VALUE
              FROM       USER_SETTING US
              JOIN       UI_SETTING S
                         ON US.I_SETTING_ID = S.I_SETTING_ID
              WHERE      S.U_SETTING_NAME = 'DATA_LOAD_EMAIL'
              AND        (US.UI_USER_UID = local_user_id
              OR         US.F_GLOBAL = 1)
              )
  LOOP
    IF local_to IS NULL THEN
    local_to := rec.U_SETTING_VALUE;
    ELSE
    local_to := local_to || ';' || rec.U_SETTING_VALUE;
    END IF;
  END LOOP
  ;
  IF local_to IS NULL  THEN
      local_to :=  'youremail@domain';
  END IF
  ;

  INSERT INTO EMAIL_LOG (MSG_FROM, MSG_TO, MSG_SUBJECT, MSG_BODY)
  VALUES (local_from, local_to, local_subject, email_message);

  --set up the connection
  local_connection :=
        demo_mail.begin_mail(sender     => local_from,
        recipients => local_to,
```

e. Find the section of the procedure as above where 'demo_mail' is called and uncomment the two lines as highlighted by removing two dashes (--).



f. Now run all the three script files in SQL*Plus. Open SQL*Plus and login as the user "poca" with the password "poca_user" and run the three script files as shown below.

```
SQL> @C:\POCA_DB_Install\full\demo_mail_pkg.sql

Package created.

Package body created.

SQL> @C:\POCA_DB_Install\full\data_access_load_proc.sql

Procedure created.

SQL> @C:\POCA_DB_Install\full\data_access_refresh_proc.sql

Procedure created.
```

g. Also, login in SQL*Plus as the user "poca" and run the following SQL commands substituting your email address in the line "set u_setting_value = 'youremail@company.domain'. Use a valid Administrator email address to replace **'youremail@company.domain'**.

```
SQL> UPDATE POCA.user_setting
      SET u_setting_value = 'youremail@company.domain'
      WHERE i_setting_id in (4060,4061,4083);

SQL> UPDATE POCA.users
      SET u_email = 'youremail@company.domain'
      WHERE u_username = 'Admin' ;

SQL> commit;
```

12. Contact the database administrator to get the ACL (Access Control List) for smtp setup. Add the ACL privilege to POCA account. This should be done by the DBA. Assumption is that the ACL name is 'smtp_acl.xml'.

```
begin
  DBMS_NETWORK_ACL_ADMIN.ADD_PRIVILEGE
('smtp_acl.xml','POCA',TRUE,'resolve');
  commit;
end;
/
begin
  DBMS_NETWORK_ACL_ADMIN.ADD_PRIVILEGE
('smtp_acl.xml',POCA,TRUE,'connect');
  commit;
end;
/
```

13. Install the Oracle Client software on the server intended to host the application. Use the Oracle Net Configuration Assistant to set up the tnsnames.ora file with an entry (as for example 'poca') for the previously established database (in step #1) and host information of the database server. For more clarifications about configuring TNS file please check deployment option #2, Step #15 below and you can manually modify the TNS file as per the configuration need.

    If Oracle Client is not installed you need to install ODP .NET software at a minimum. Oracle 11g/12c client comes with ODP.NET as default.
    There are two ways to install the ODP .NET software:
    a. (Recommended) During installation select the installation type "Administrator". This ensures that the "Oracle Data Provider for .NET" is installed, (or)
    b. Select the "Custom" type. If this option is chosen, "Oracle Data Provider for .NET" must be manually selected to be included in the installation.

14. Next, create the POCA application. Refer to the section 4 later in this guide for "Installing the Application".

3.2 OPTION # 2 Deployment

DEPLOYING THE DATABASE AND APPLICATION ON ONE SERVER OR PC

Here are the steps that create the database and install the application. The steps are provided for the benefit of those who are not familiar with installing Oracle software. You can go to Oracle site for detailed information and more clarifications.

To create the POCA database successfully, you need:

1. One of the Windows servers/PCs with Windows 2012, Windows 2003, Windows 7, Windows 8 or Windows 10 installed, with at least 4 GB available for the POCA database, and the following Oracle Products are already installed:
   Oracle database 12c R1
2. POCA Public release install package (downloadable form FDA web site).

The Oracle database software on the computer should be installed by a user with Administrator rights. To check user rights, go to Control Panel and click on User Accounts.

The User Accounts dialog will appear. Locate your name in the User Name column of the Users for this Computer field. Once found, check your access rights in the Group column. It should be set to Administrators.

Creating POCA Directories

To create POCA directories you need to:

1. If installing to a drive other than C: drive, substitute the appropriate drive letter in all of the path names mentioned in the instructions and in the scripts provided. However, to make it simple, it is advisable to install the software to C: drive.
2. Download the zip file and extract in your local drive. Copy the folder POCA_DB_Install from the extracted file to the C: drive.
3. Create 'poca_data_import' folder in your local drive as C:\poca_data_import.

   Copy the file 'drugsatfda_20160922_New.txt' from the C:\ POCA_DB_Install \POCA_Datasources directory to the C:\poca_data_import **d**irectory.

   Copy the file 'rxnorm_20160905_New.txt' from the C:\ POCA_DB_Install \POCA_Datasources directory to the C:\poca_data_import **d**irectory.

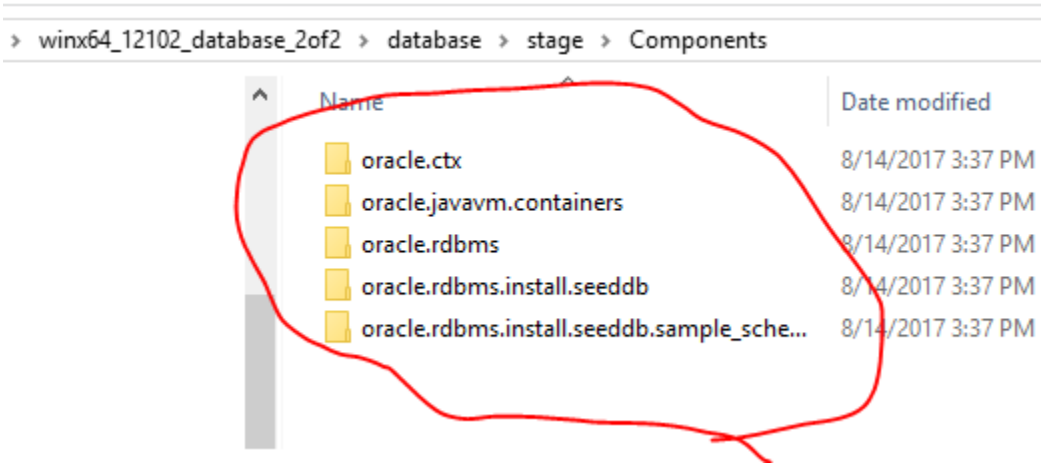
   Copy files related to other data sources also in the same way.

4. Create a folder 'Dump_dir' under C drive. Place the database dump file 'POCAPUB.dmp' from the C:\POCA_DB_install\full to C:\Dump_dir directory.

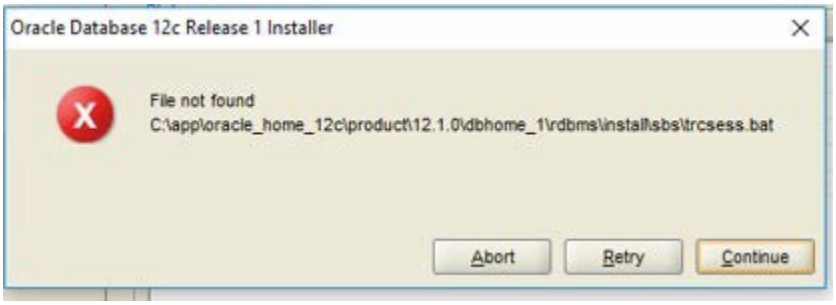
Creating POCA database on a Windows PC or Server

The following instructions are created based on the assumption that the Oracle Database 12c software will be installed on Windows.

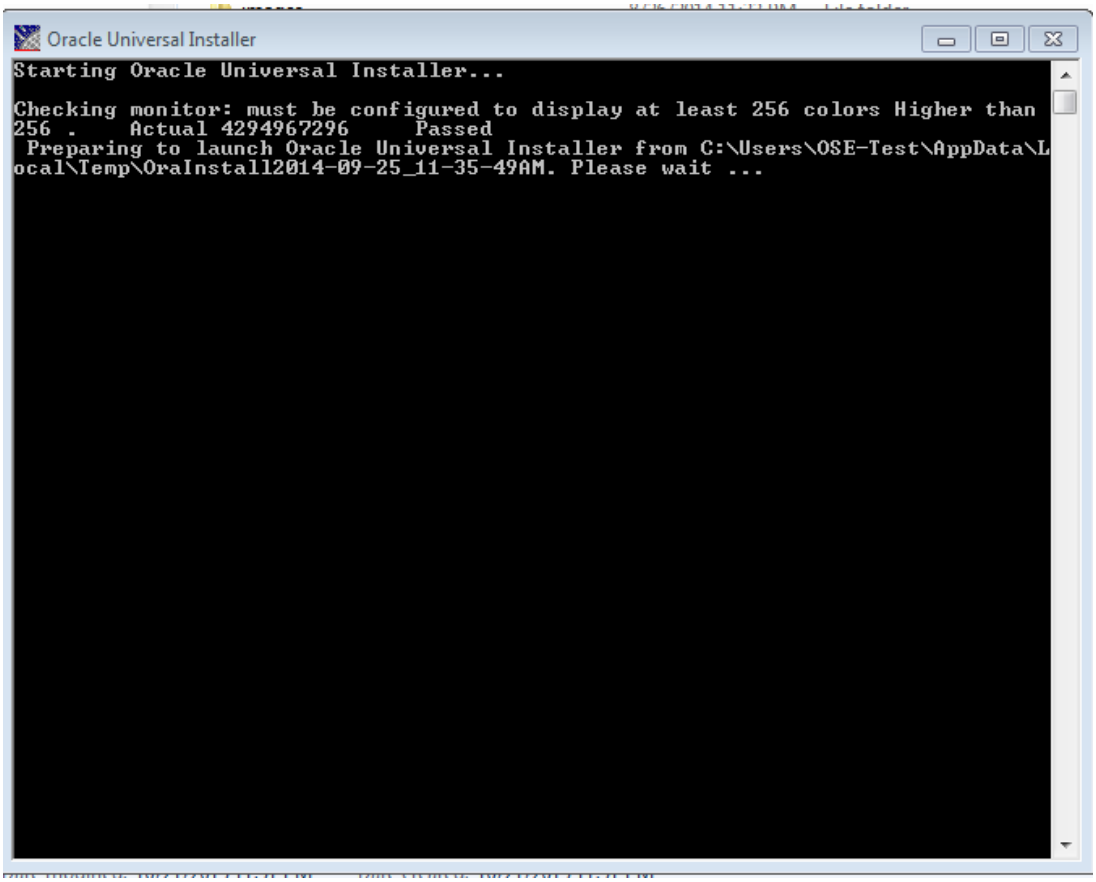
1. Download Oracle 12c R1 Standard or Enterprise Edition. Unzip all the files in a folder under your local drive (e.g. C drive).
2. After unzip, there will be 2 folders created name similar like “1 of 2” and “2 of 2”. Copy all files from “2 of 2 folder”\database\stage\Components to “1 of 2 “\database\stage\Components.



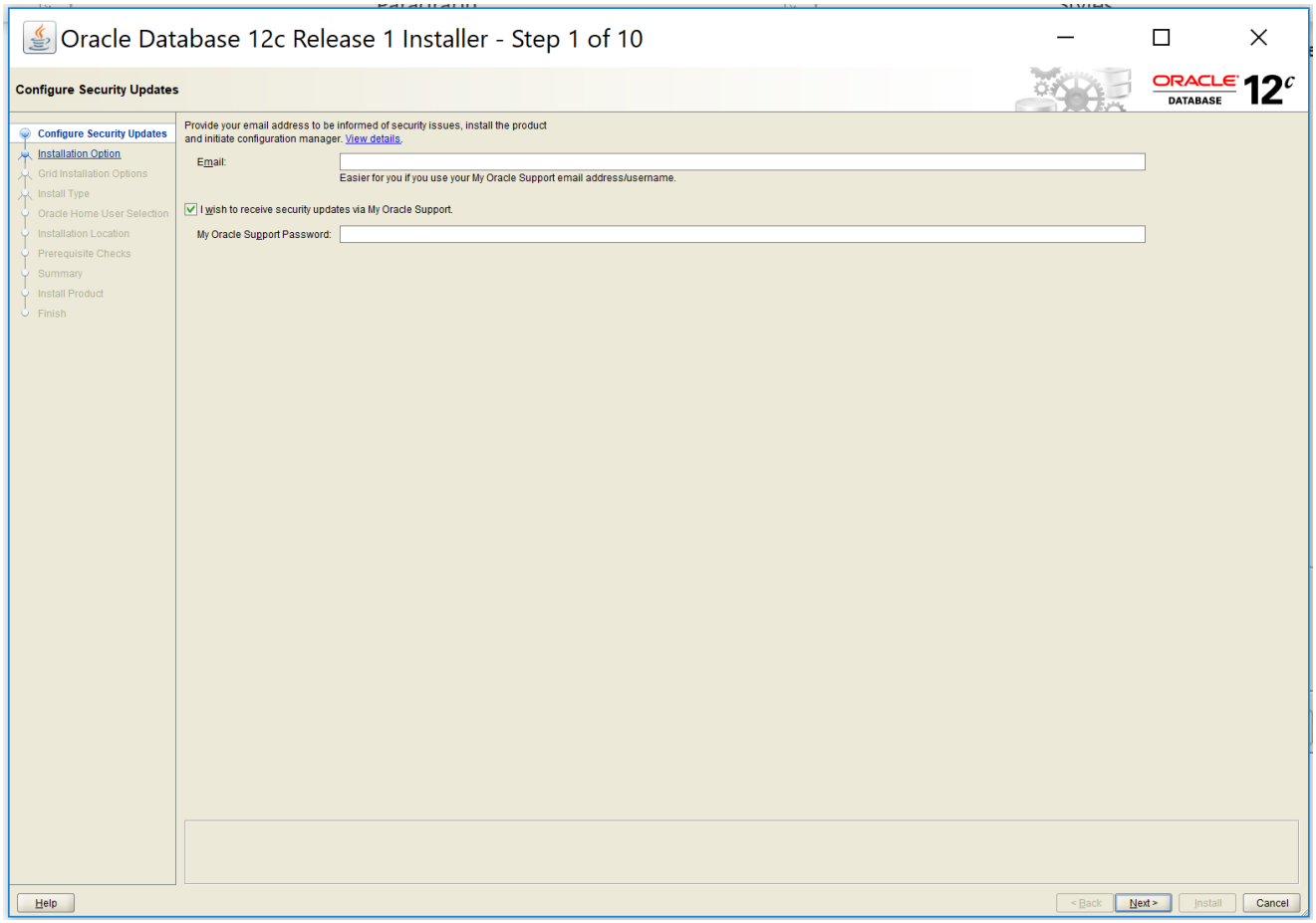
If you fail to copy files you will get this error while database configuration step. In that case copy the files as described above and re-install.



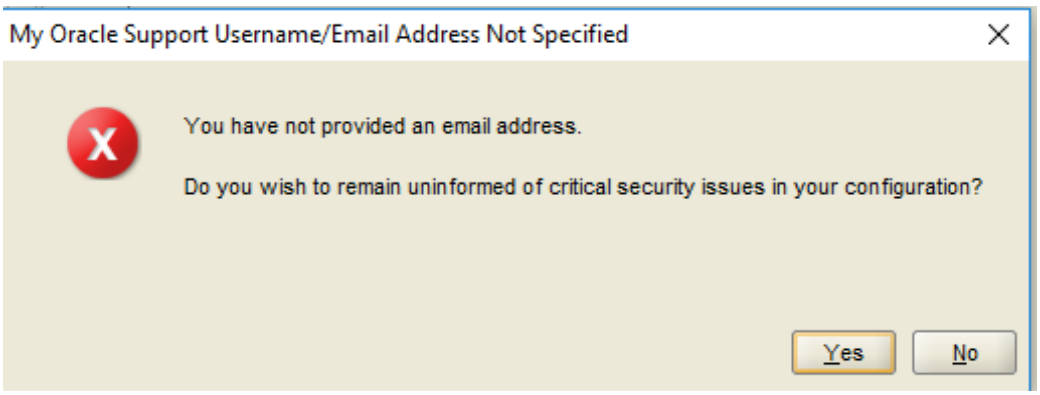
3. Run the setup.exe from the extracted folder to install Oracle software and database.



4. After completing the initial setup it will open the following window. Enter your email address, if you want, but it is not necessary. If you do not have any oracle support account, it is recommended not to check “I wish to receive security updates ….” and Click “Next” to continue.

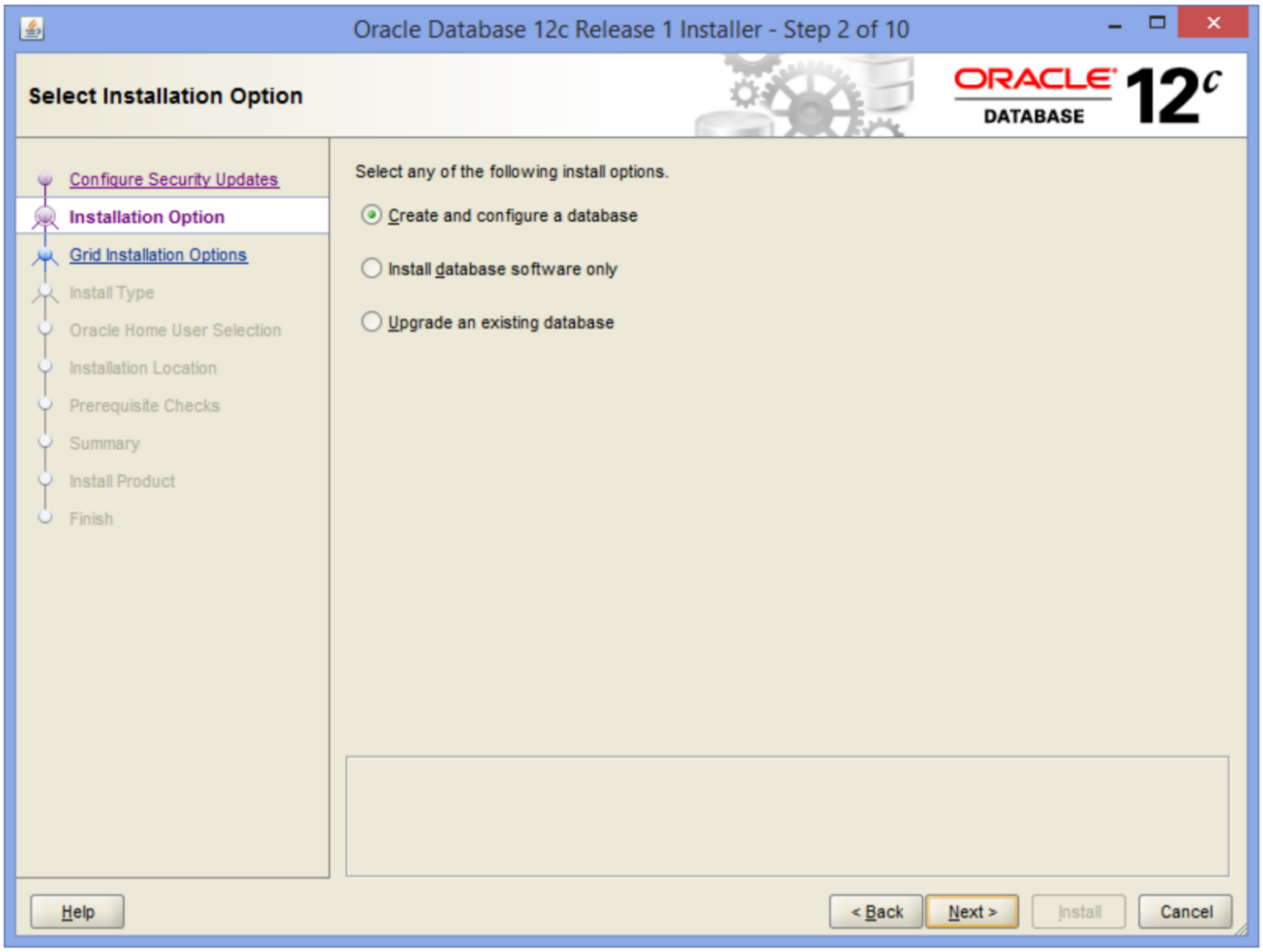


5. A pop-up window will appear if you do not provide your email address and click yes.

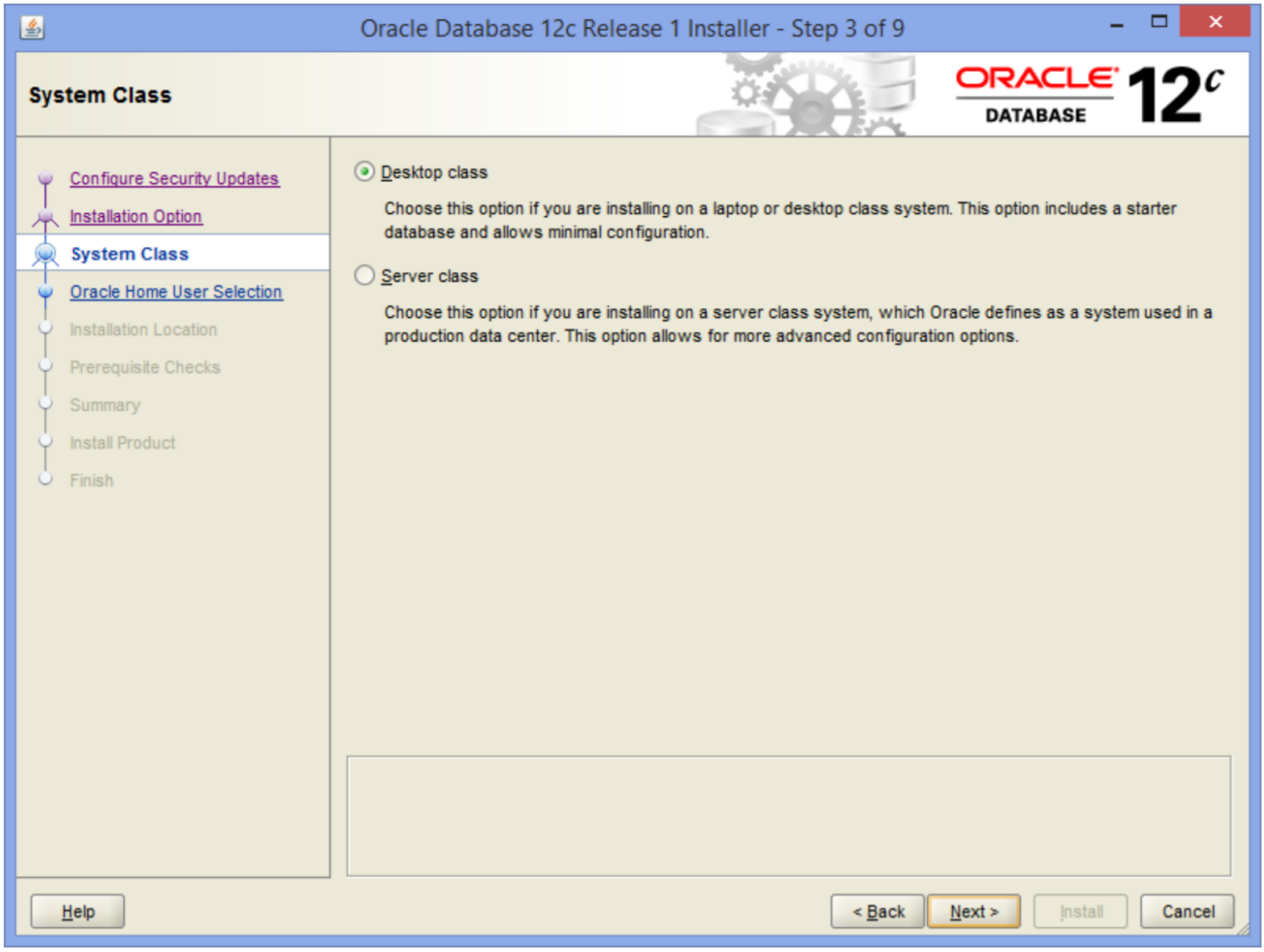


6. Select the option 'Skip software updates' if you don't have any Oracle Support credentials. Click Next to continue.

7. Check the option 'Create and configure a database. Click Next.



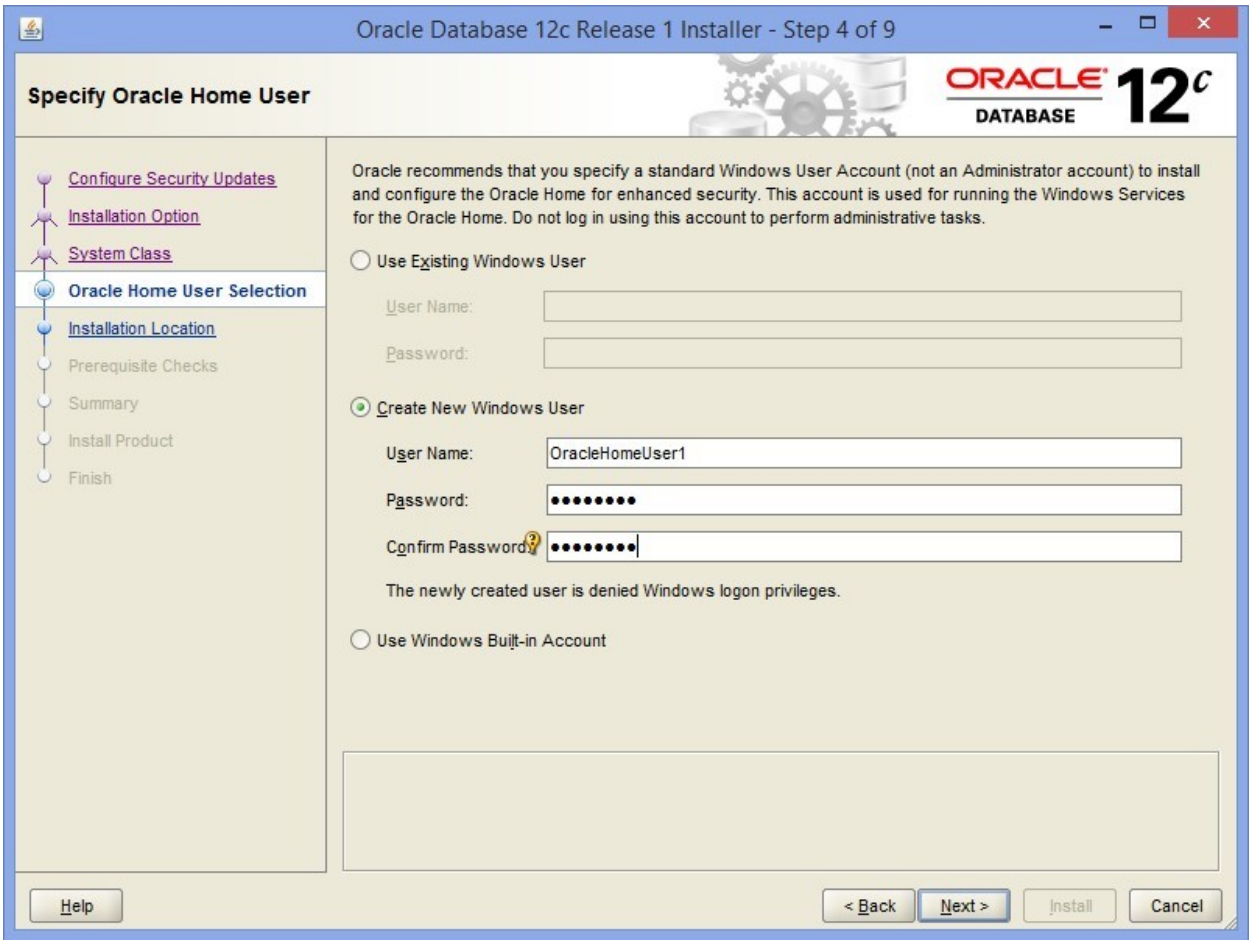
8. Select 'Desktop Class' option and click Next



9. The window provides the following options:

- If you select "Use Existing Windows User", the user credentials provided must be a standard Windows user account (not an administrator).
    - If this is a single instance database installation, the user can be a local user, a domain user, or a managed services account.
    - If this is an Oracle RAC database installation, the existing user must be a Windows domain user. The Oracle installer will display an error if this user has administrator privileges.
- If you select "Create New Windows User", the Oracle installer will create a new standard Windows user account. This user will be assigned as the Oracle Home User. Please note that this user will not have login privileges. This option is not available for an Oracle RAC Database installation.
- If you select "Use Windows Built-in Account", the system uses the Windows Built-in account as the Oracle Home User.

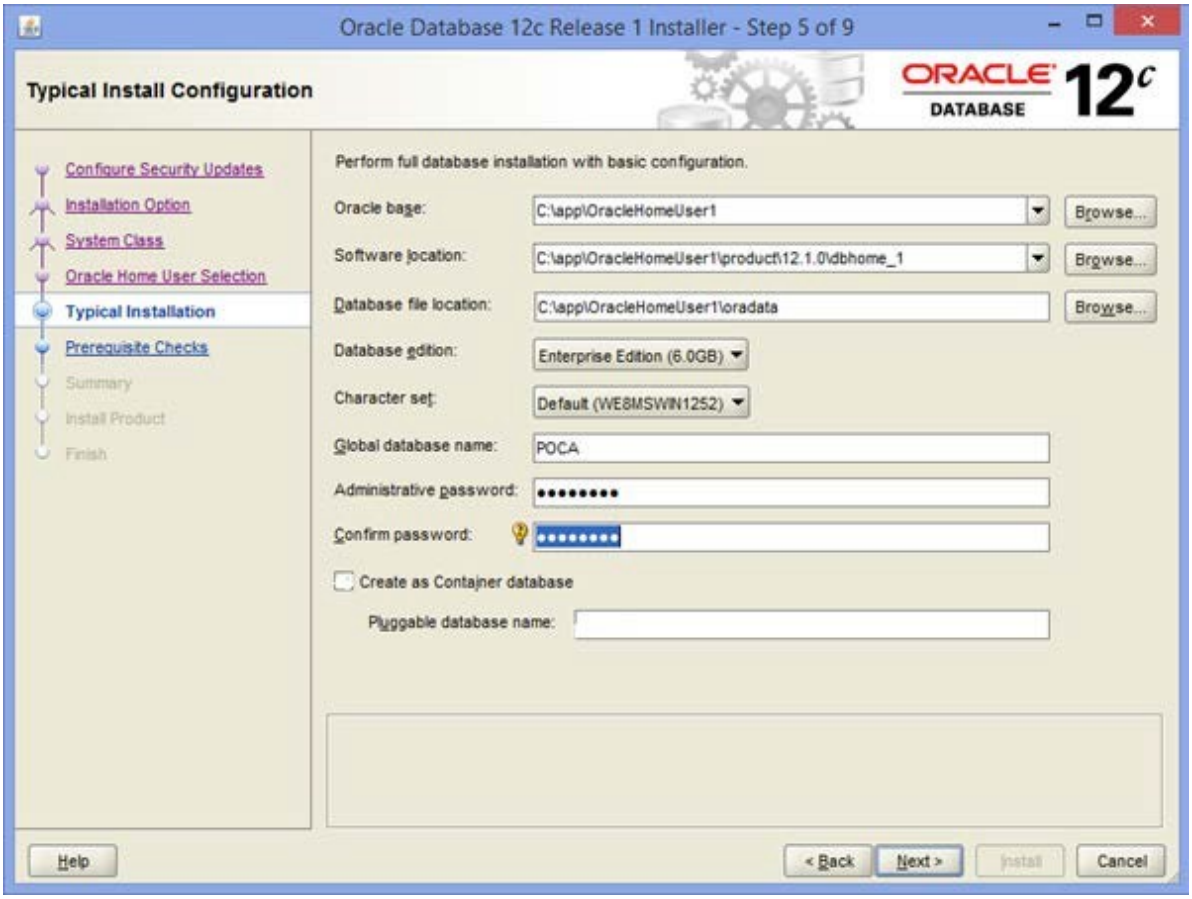
Select the **Create New Windows User** option. Enter the user name as **OracleHomeUser1** and password as **Welcome1**. Click **Next**.



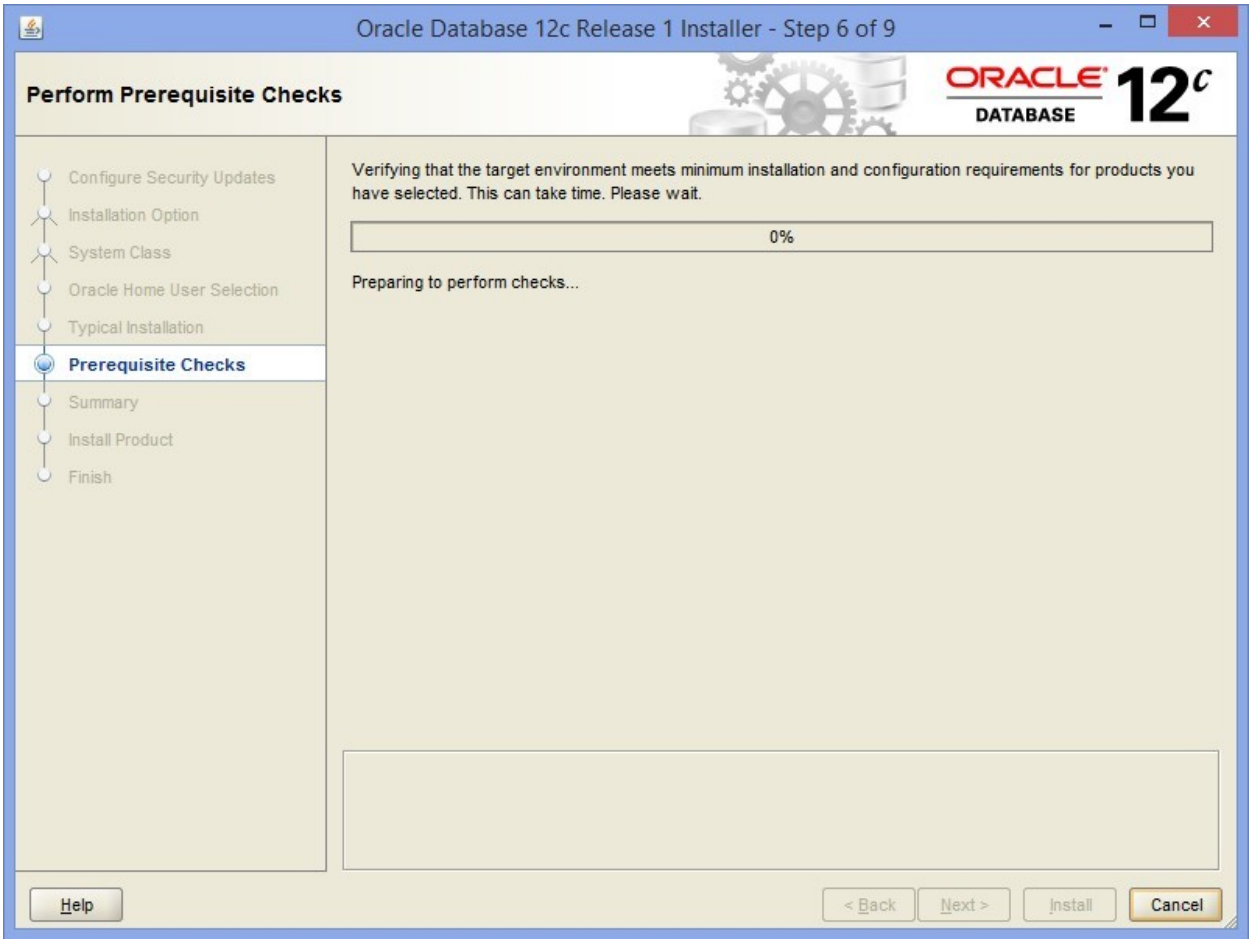
10. Step 5 of the installation is important because it determines the Oracle Home location, database, and database admin password. Whatever location comes by default, will be created automatically during installation. No need to create the folders manually. Type Global database name as 'POCA'. Create an Administrative password and confirm the same password. Please note down the password because it is required to complete all the additional steps later. This password will be used later to log into administrator accounts such as SYS and SYSTEM.

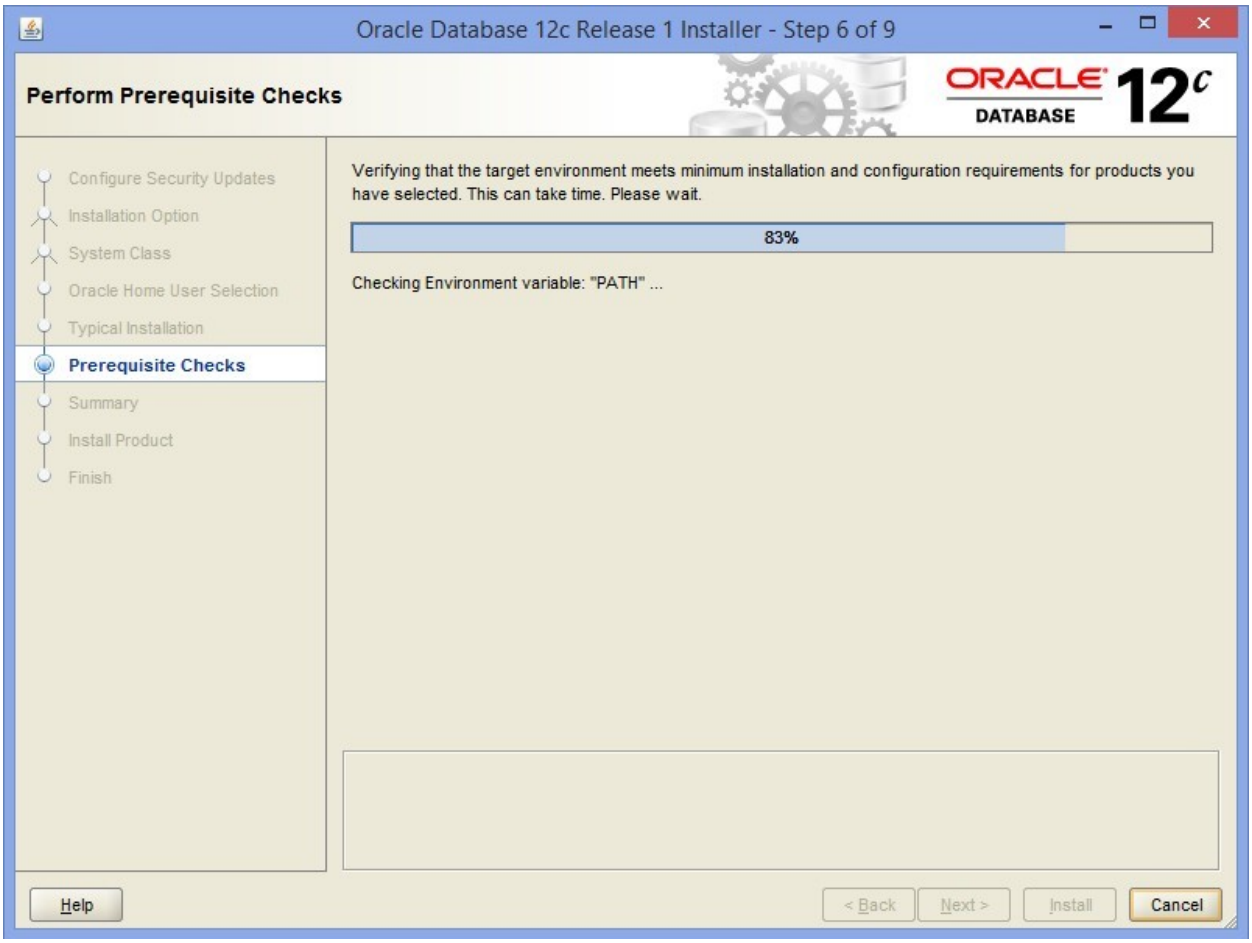
    Note: DO NOT check box "Create as Container database".

    Click Next

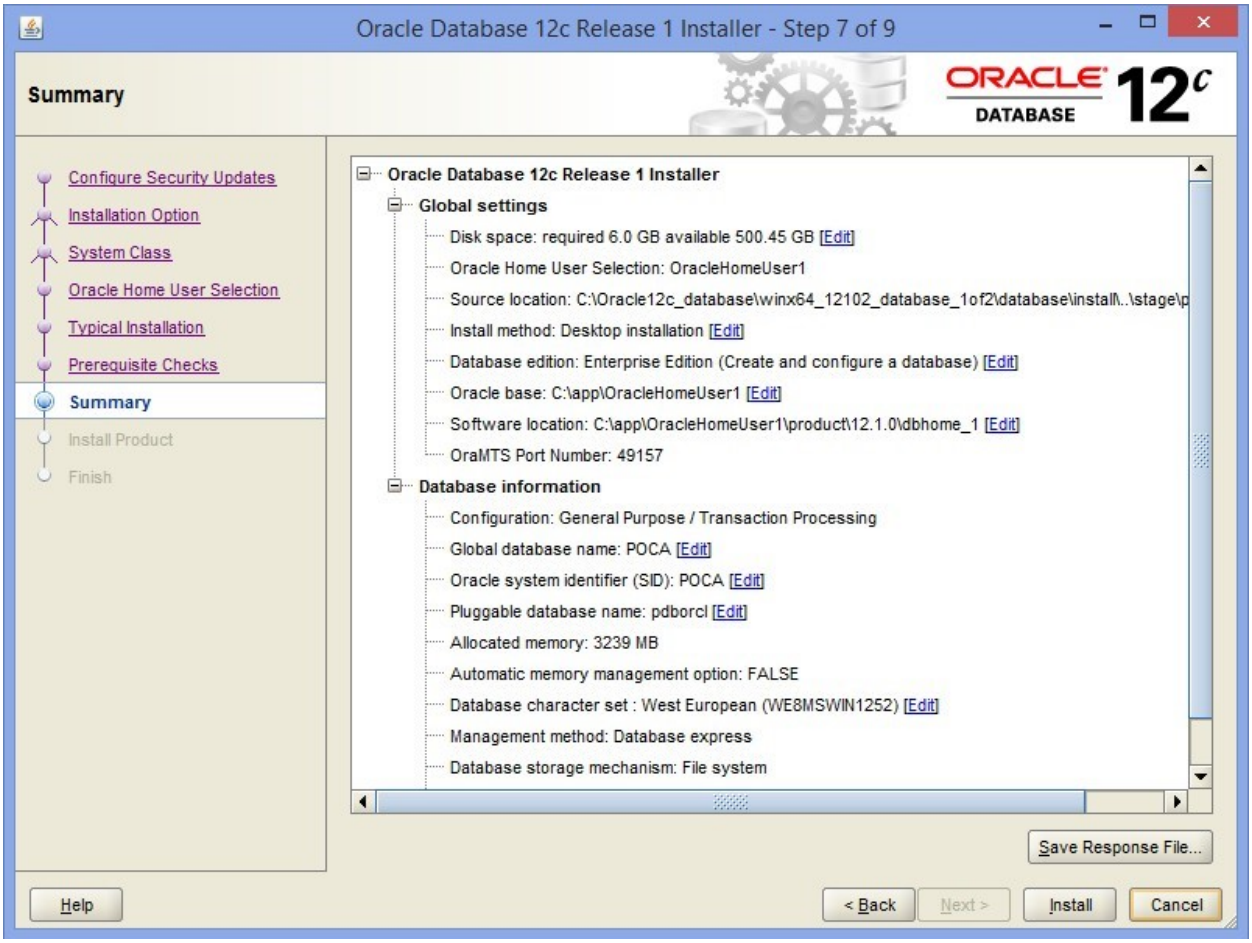


11. Step 6 will perform prerequisite checks. Once it is finished, it will move to next step.

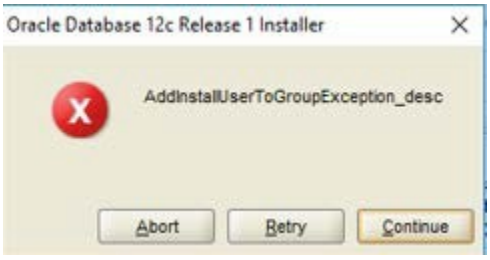


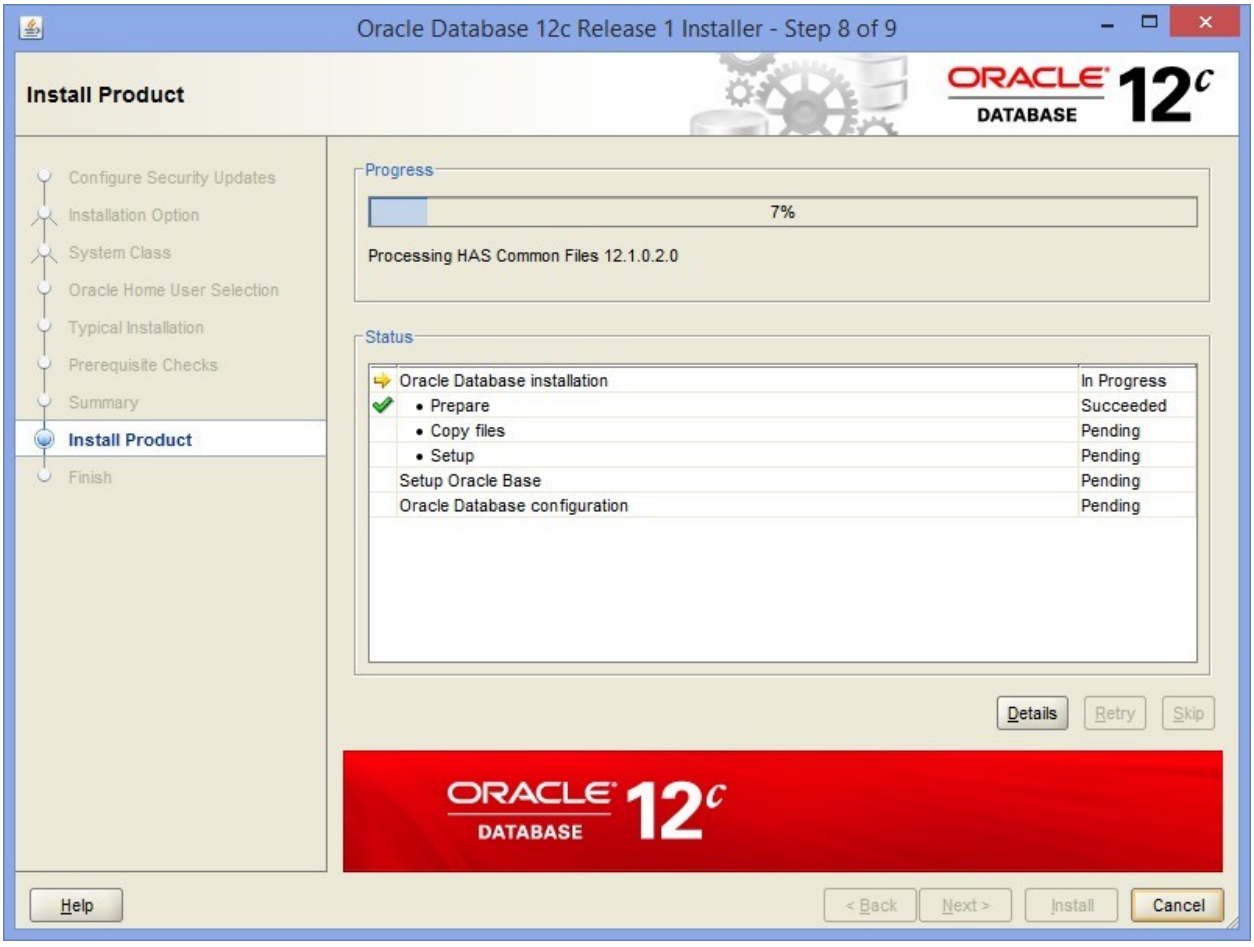

Oracle Database 12c Release 1 Installer - Step 6 of 9
Perform Prerequisite Checks
ORACLE DATABASE 12c
Configure Security Updates
Installation Option
System Class
Oracle Home User Selection
Typical Installation
Prerequisite Checks
Summary
Install Product
Finish
Verifying that the target environment meets minimum installation and configuration requirements for products you have selected. This can take time. Please wait.
83%
Checking Environment variable: "PATH" ...
Help
< Back
Next >
Install
Cancel

12. Click on “Install” to start installing the software.

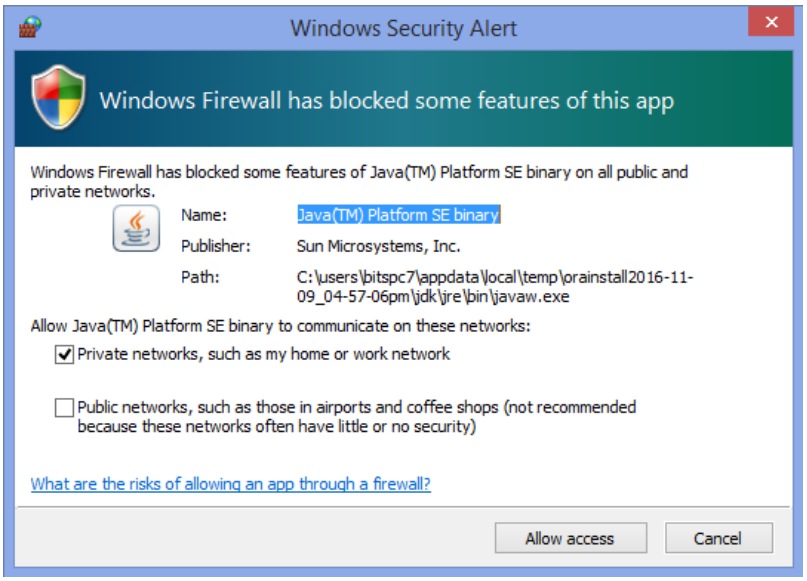


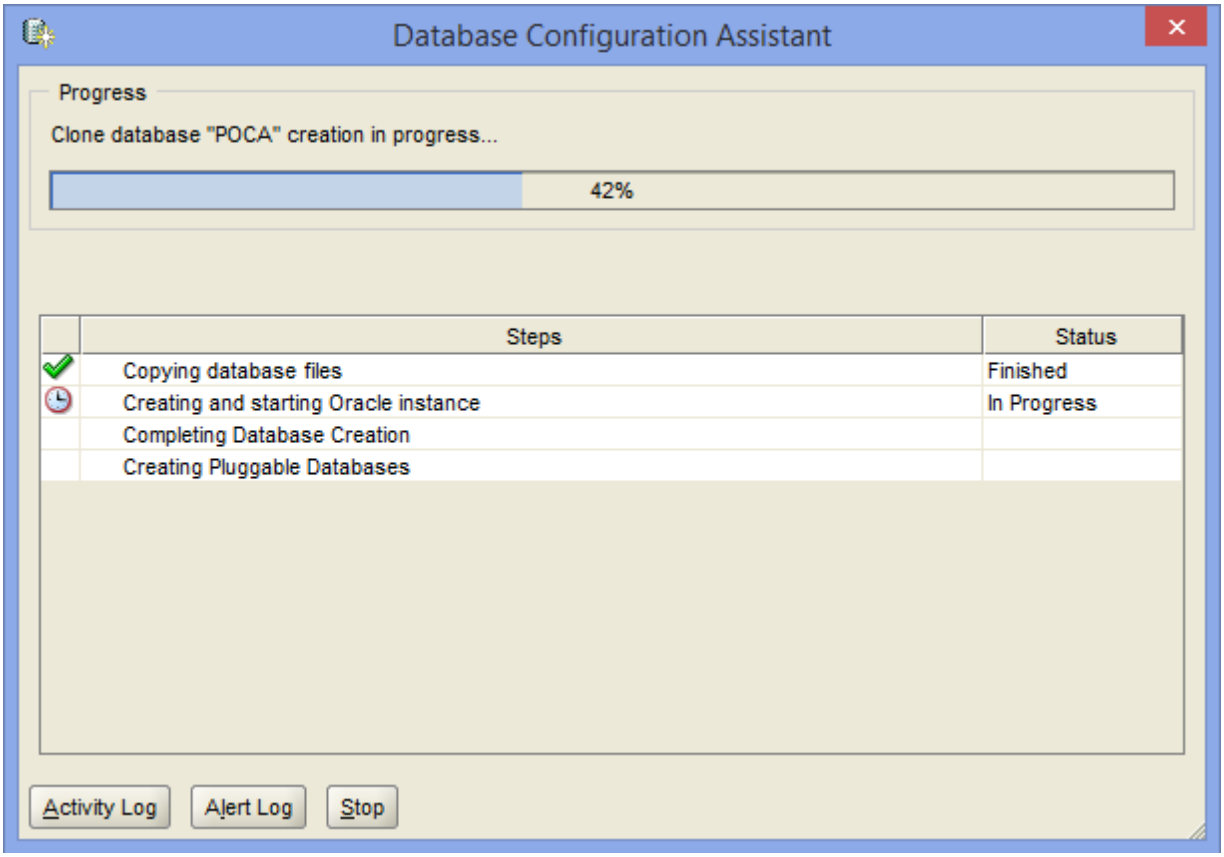
13. The progress window appears. Next Step will create the database, configure the database. In some version of windows, you may get this error. Just click “continue” button multiple times and it will go.

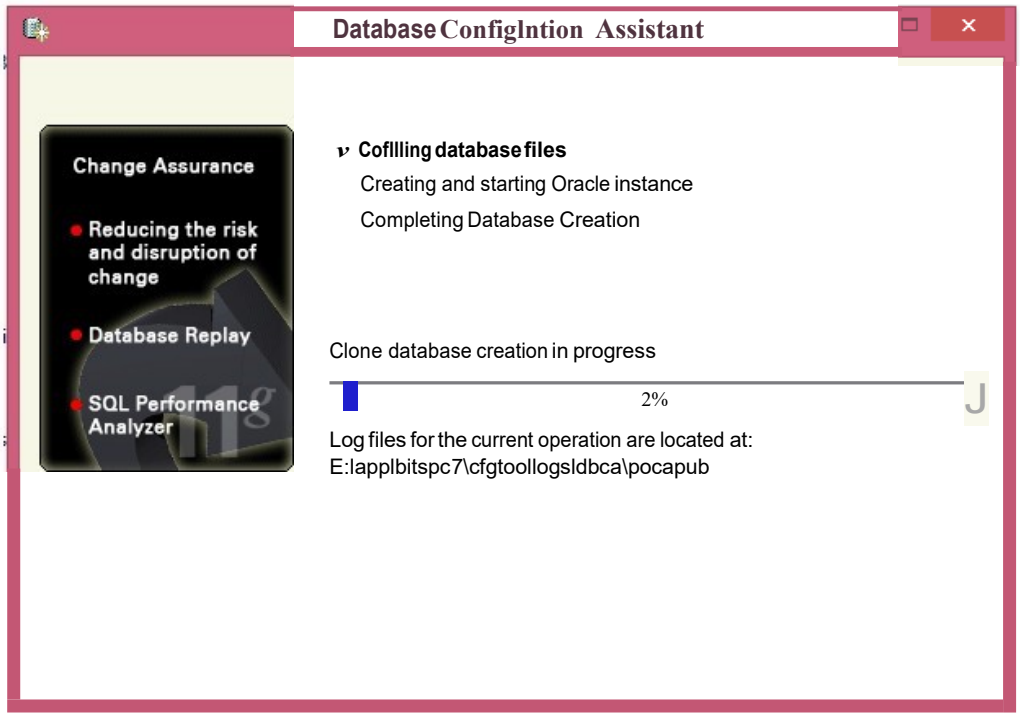




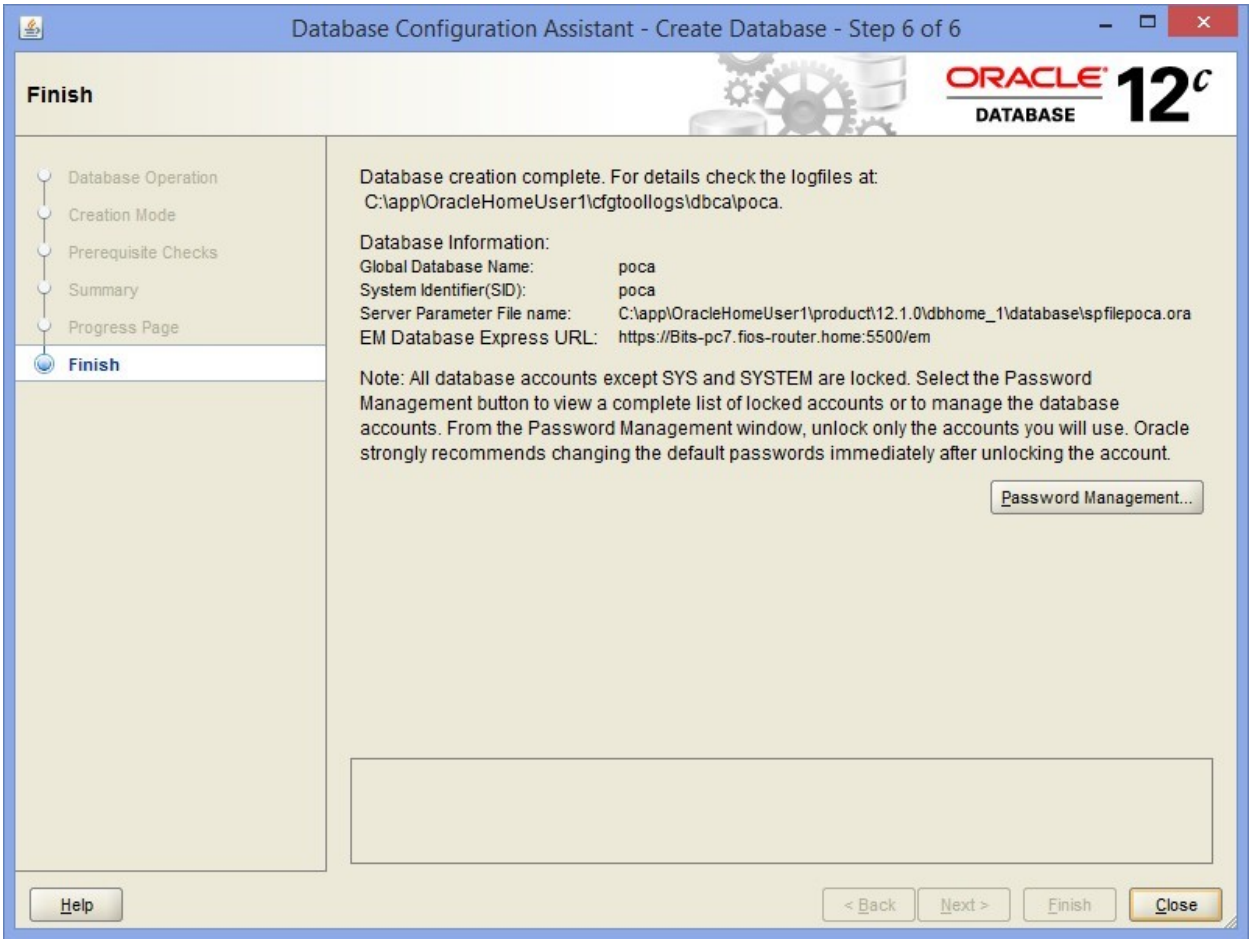
Click on ‘Allow Access’


Windows Security Alert
Windows Firewall has blocked some features of this app
Windows Firewall has blocked some features of Java(TM) Platform SE binary on all public and private networks.
Name: Java(TM) Platform SE binary
Publisher: Sun Microsystems, Inc.
Path: C:\users\bitspc7\appdata\local\temp\orainstall2016-11-09_04-57-06pm\jdk\jre\bin\javaw.exe
Allow Java(TM) Platform SE binary to communicate on these networks:
Private networks, such as my home or work network
Public networks, such as those in airports and coffee shops (not recommended because these networks often have little or no security)
What are the risks of allowing an app through a firewall?
Allow access
Cancel


Database Configuration Assistant
Progress
Clone database "POCA" creation in progress...
42%
Steps
Status
Copying database files
Finished
Creating and starting Oracle instance
In Progress
Completing Database Creation
Creating Pluggable Databases
Activity Log
Alert Log
Stop

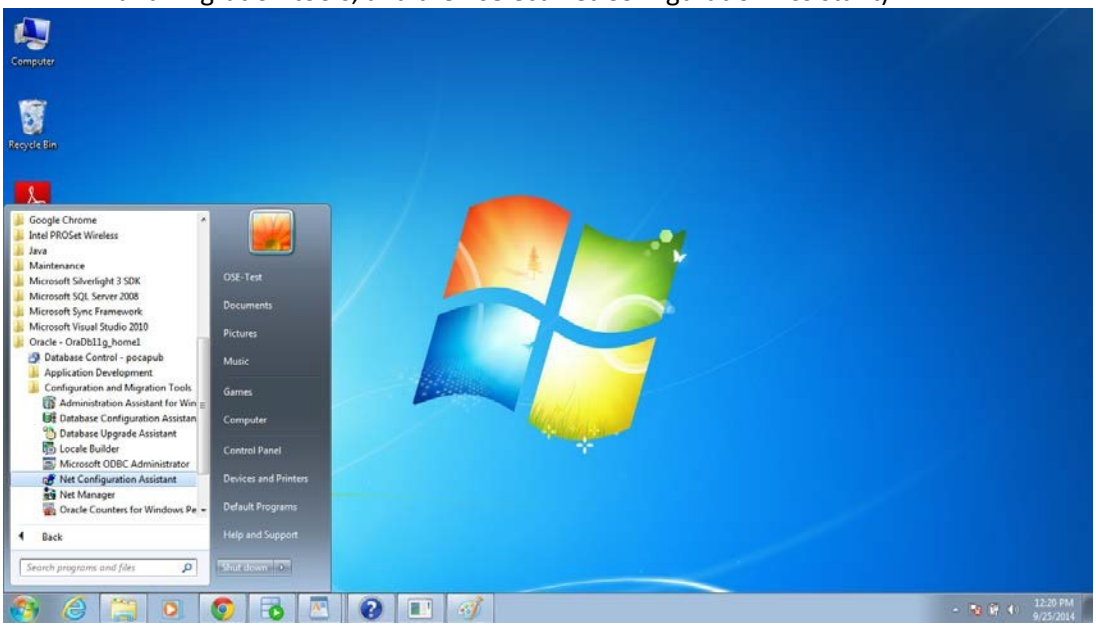

Database ConfigIntion Assistant
Change Assurance
Reducing the risk and disruption of change
Database Replay
SQL Performance Analyzer
Cofillling database files
Creating and starting Oracle instance
Completing Database Creation
Clone database creation in progress
2%
Log files for the current operation are located at:
E:lapplbitspc7\cfgtoollogsldbca\pocapub

14. This is the summary of the database (e.g. poca) installed. Click Close to exit.

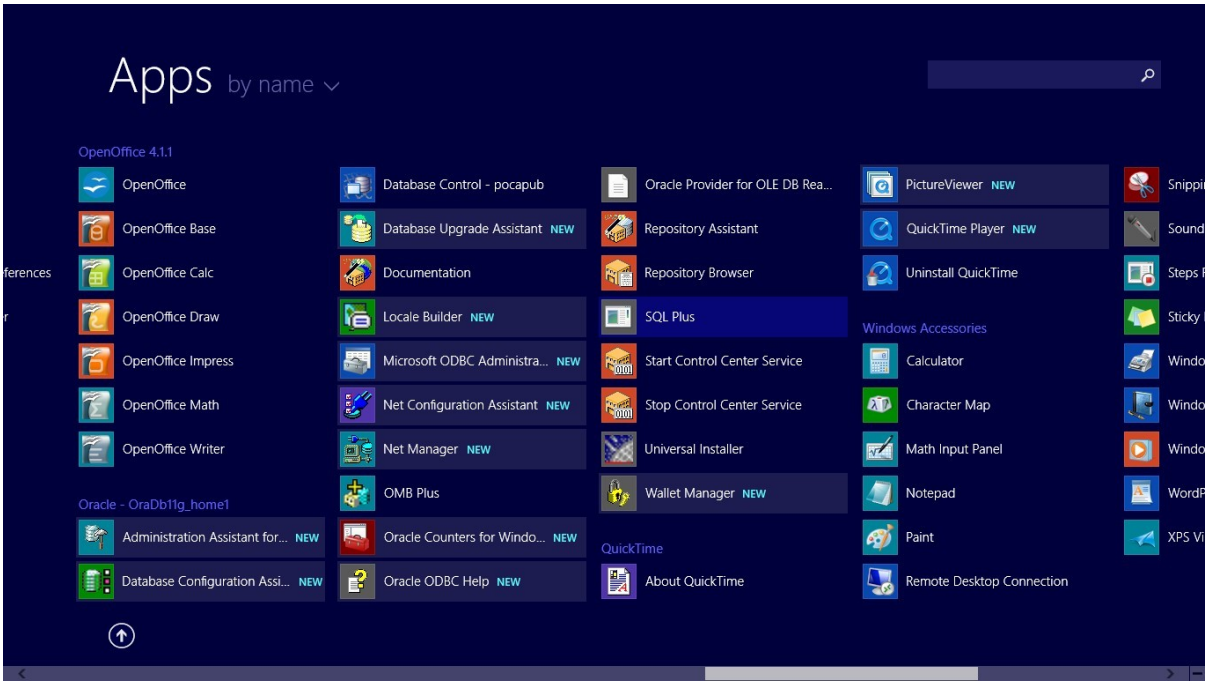


15. This is the final step explains the database installation is successful.

16. Create a tnsnames.ora entry for the database. (**This step is optional. if you want a new TNS entry otherwise skip this step**)
    a. Run the Oracle Net Configuration Assistant if you are not already on the Welcome Screen from the previous step. Select: (start, Oracle- OraDb12c_home1, Configuration and Migration tools, and then select Net Configuration Assistant)

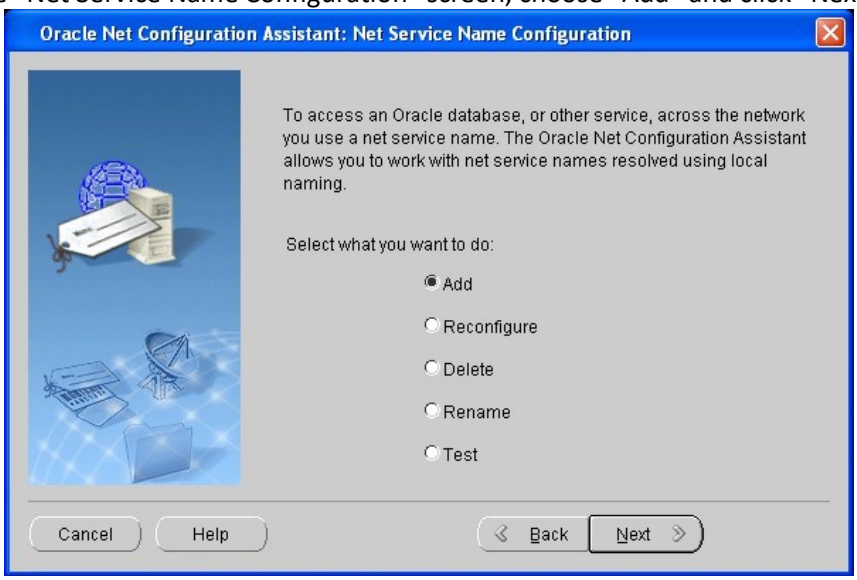


In case of **Windows 8** The screen will look like as below

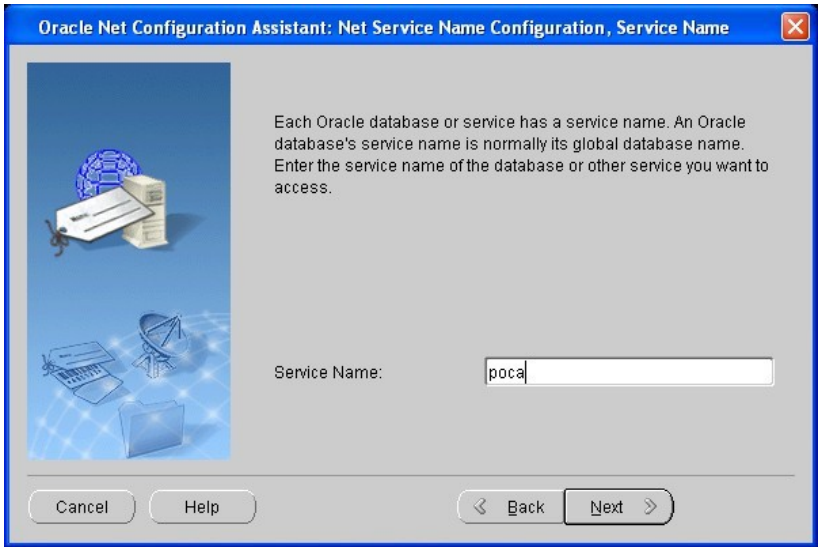


b. User Account Control screen appears. Select yes to allow access to make changes to this computer: On the “Welcome” screen, choose “Local Net Service Name configuration” and click “Next.”

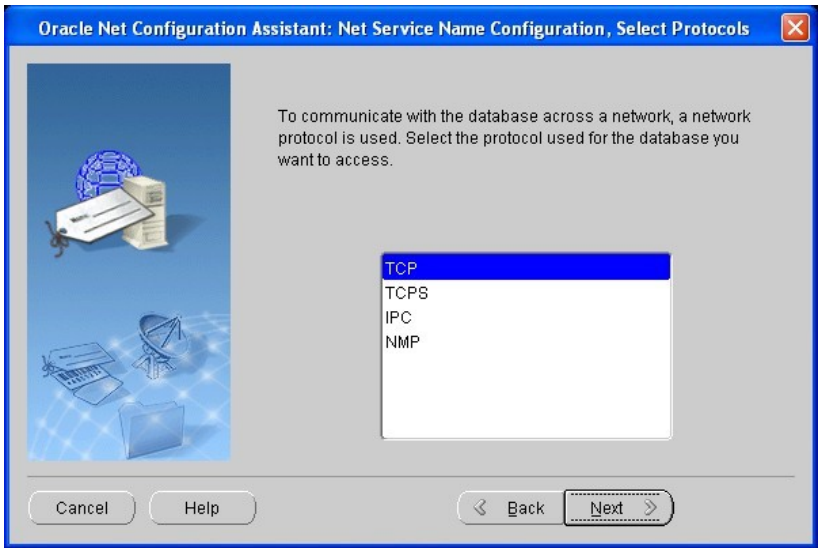
c. On the “Net Service Name Configuration” screen, choose “Add” and click “Next.”



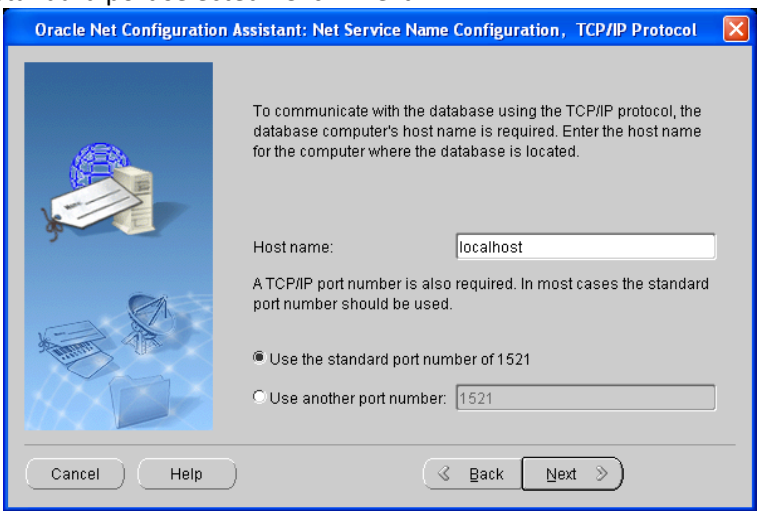
d. On the “Net Service Name Configuration, Service Name” screen, type the Service Name “poca” and click “Next.”



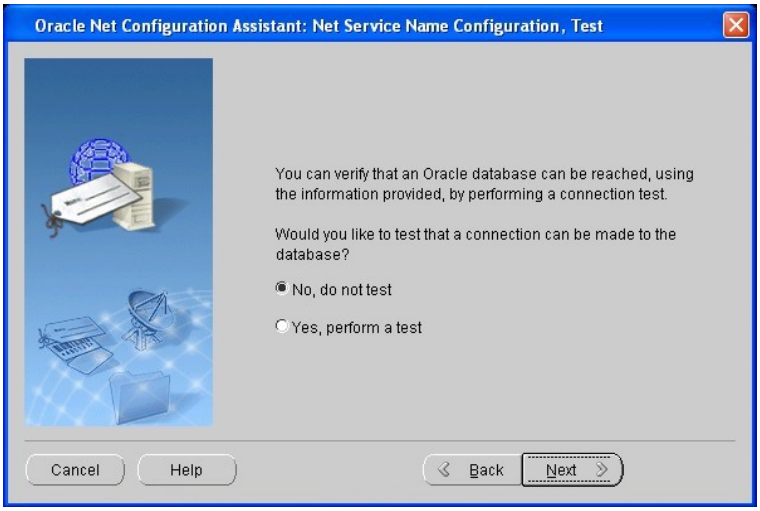
e. On the “Net Service Name Configuration, Select Protocols” screen, leave “TCP” selected and click “Next.”



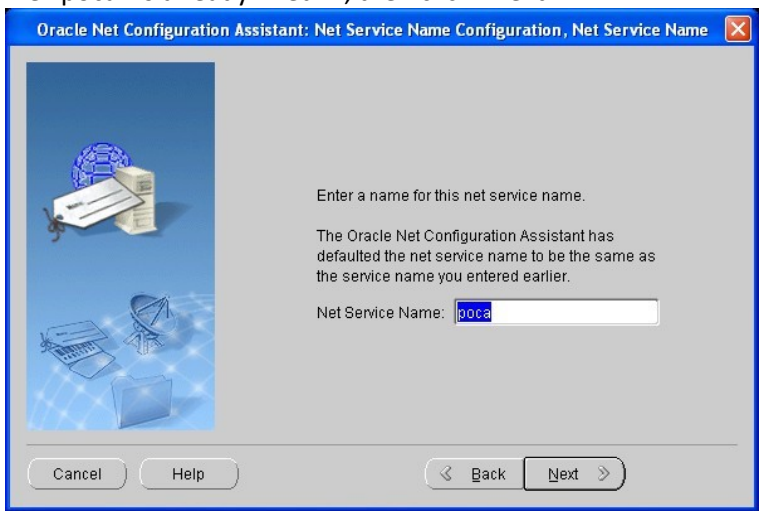
f. On the “Net Service Name Configuration, TCP/IP Protocol” screen, type “localhost” and leave the standard port selected. Click “Next.”



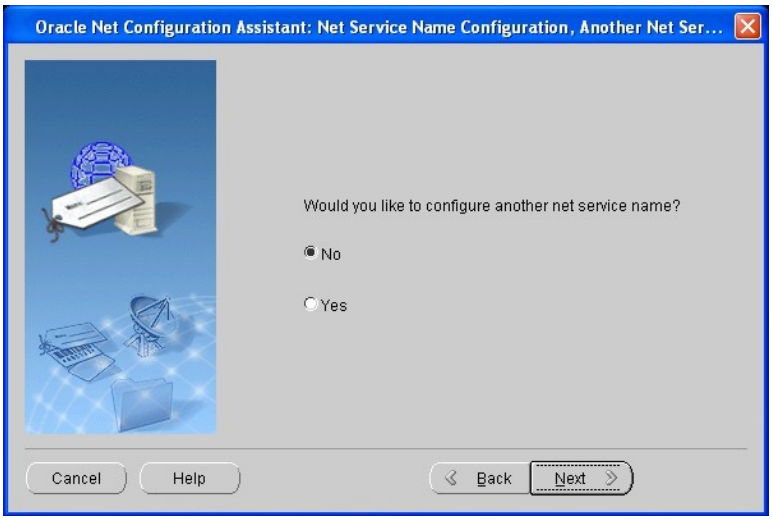
g. On the “Net Service Name Configuration, Test” screen, do not perform a test. Click “Next.”



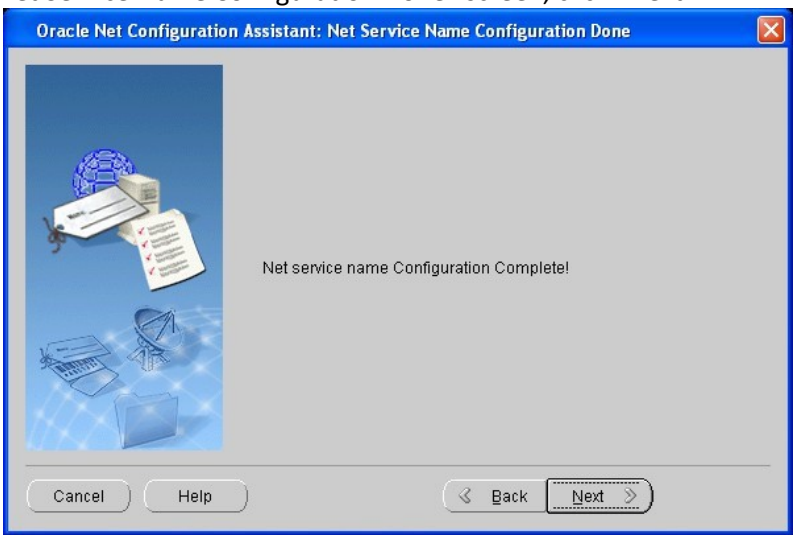
h. On the “Net Service Name Configuration, Net Service Name” screen, ensure the Net Service Name “poca” is already filled in, then click “Next.”



i. On the “Net Service Name Configuration, Another Net Service Name?” screen, answer “no” and click “Next.”



j. On the “Net Service Name Configuration Done” screen, click “Next.”



k. You will be returned to the “Welcome” screen. Click “Finish.”

Create the POCA database user and import POCA data.

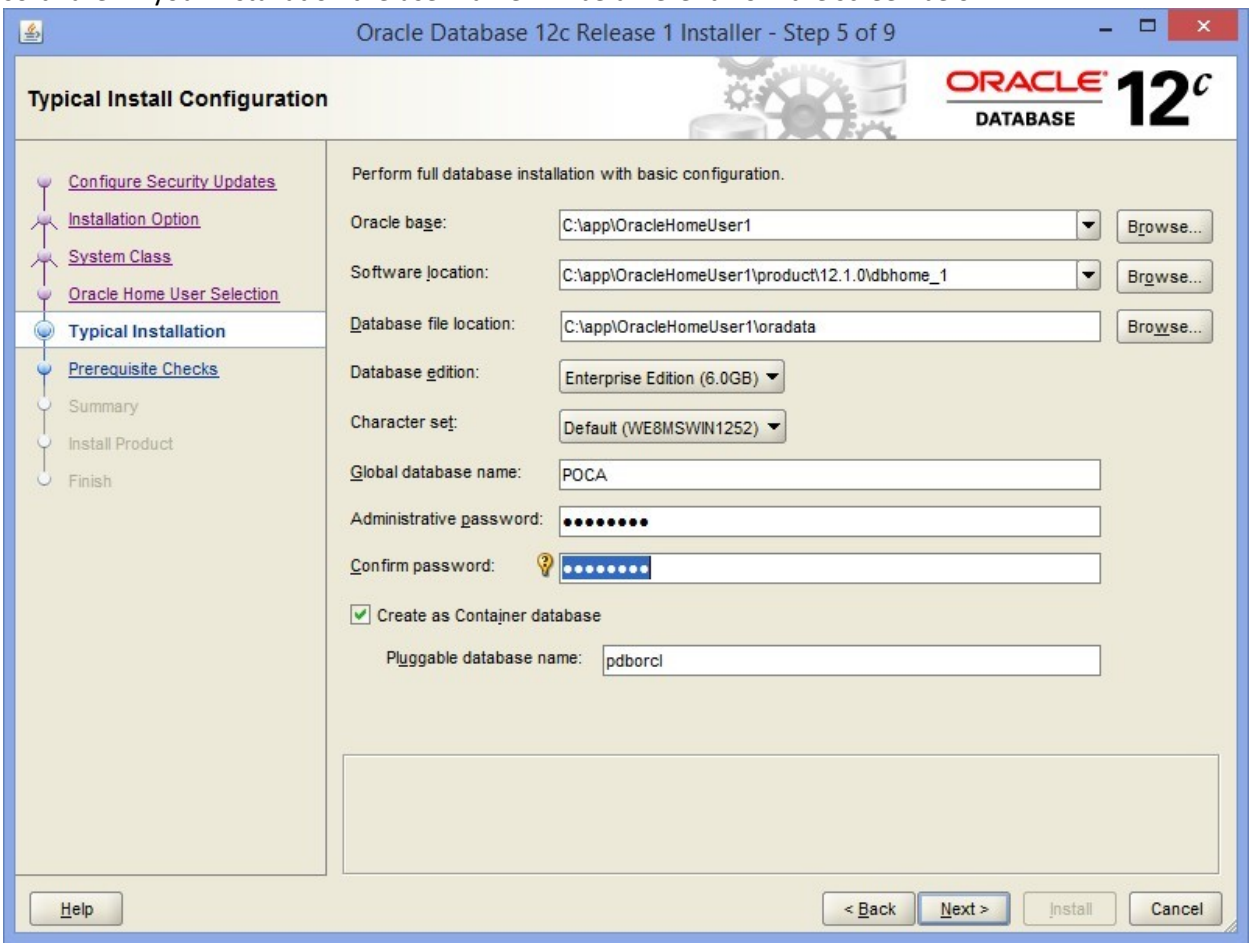
1. The script file named 'create_POCA.sql' is available in the directory 'POCA_DB_Install\full'. It is required to customize the script as the path names (highlighted below) differ from the script provided. To customize the create_POCA.sql script:
    a. Open the script in Notepad.
    b. The section 'C:\app\oracleHomeUser1\oradata\POCA\' needs to be modified based on 'Oracle Home' Location and Database configuration. Please check your Oracle software installed location. Also see software location on the diagram 5.5 below. As per screen below the correct path in the script 'create_poca.sql' and it will be as 'Database file location\Global database name\'. DO NOT REMOVE 'poca_data.dbf', this file will be created in this step.
    c. In this script the user 'poca' will be created. The default password is poca_user. If the default settings are being used then proceed to the next step. The password can be changed, if required.
    d. Save your changes and close the script.

create_poca.sql - Notepad

File Edit Format View Help

```
spool C:\POCA_DB_Install\cr_POCA.log
REM ******************************************************
REM All references to directories will need to be changed
REM to match the directory structure of the server
REM
REM *** RUN THIS SCRIPT AS SYS USER ***
REM
REM ******************************************************

REM Create FDA tablespaces
drop tablespace FDA including contents and datafiles;
create tablespace FDA
   datafile 'C:\app\oracleHomeUser1\oradata\POCA\poca_data.dbf' size 2000M REUSE AUTOEXTEND ON MAXSIZE 3000M;
DROP USER POCA CASCADE;
create user poca identified by poca_user;
grant create session to poca ;
grant dba to poca ;
REM ***************************************
REM * set default tablespace and
REM * temporary tablespace for user poca.
REM ***************************************
alter user poca
   default tablespace FDA
   temporary tablespace temp
   quota unlimited on FDA;
grant execute on sys.dbms_session to poca;
grant execute on sys.dbms_sql to poca;
grant execute on sys.dbms_output to poca;
grant execute on sys.dbms_job to poca;
grant select on sys.dba_users to poca;
grant select on sys.dba_jobs to poca;
grant select on sys.dba_views to poca;

REM
REM Create pocaadmin role and grant permissions to this role
REM
/*
create role pocaadmin identified by pocaadmin;
```

Example: Diagram: In this diagram 'OSE-Test' is the window user name who installed the Oracle software. In your installation the user name will be different from the screen below.



2. If all the default settings were used in the previous step# 1, then proceed to Step 2c to run the command C:\POCA_DB_Install\full\import_poca.bat. If any of the settings were customized (e.g. password is changed), then the import_poca.bat script will also need to be customized. To customize the C:\POCA_DB_Install\full\import_poca.bat script:

    a. If you are comfortable providing user/password@connect_string when prompted, double-clicking on import_poca.bat file.

    b. **Do not double-click on the import_poca.bat script if you don't want to provide username, password details when prompted**! In the Windows environment, double-clicking on a .bat file will cause Windows to execute the file. To open , edit the **import_poca.bat** script in Notepad:
        i. Right-click on the file name (a pop-up menu is displayed).
        ii. Select the Edit option from the pop-up menu (this will open a Notepad session

for the selected file);

iii. Make appropriate changes by providing the user name, password, and the database name (if other than default settings are used) in the format username/password@connect_string. (default settings are user name poca, password poca_user, and database name poca.)

iv. Save your changes and close the script.

c. To execute the C:\POCA_DB_Install\full\import_poca.bat script, double-click on the file icon in Windows Explorer.

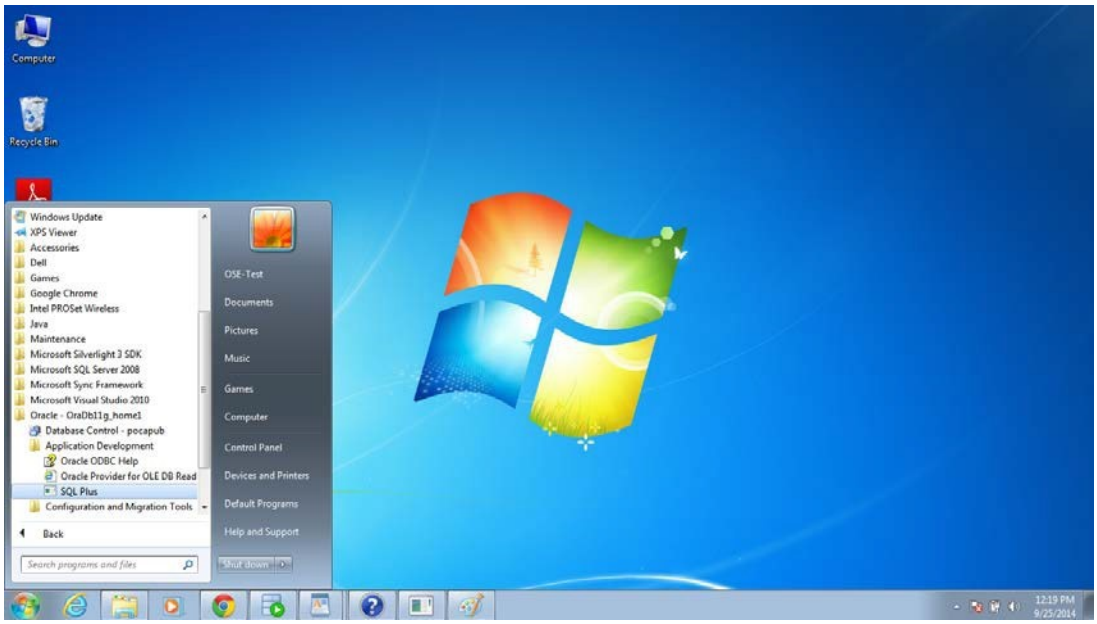
(OPTIONAL)

3. In case you need to run the create_POCA.sql script you need to connect to the database using SQL*Plus.

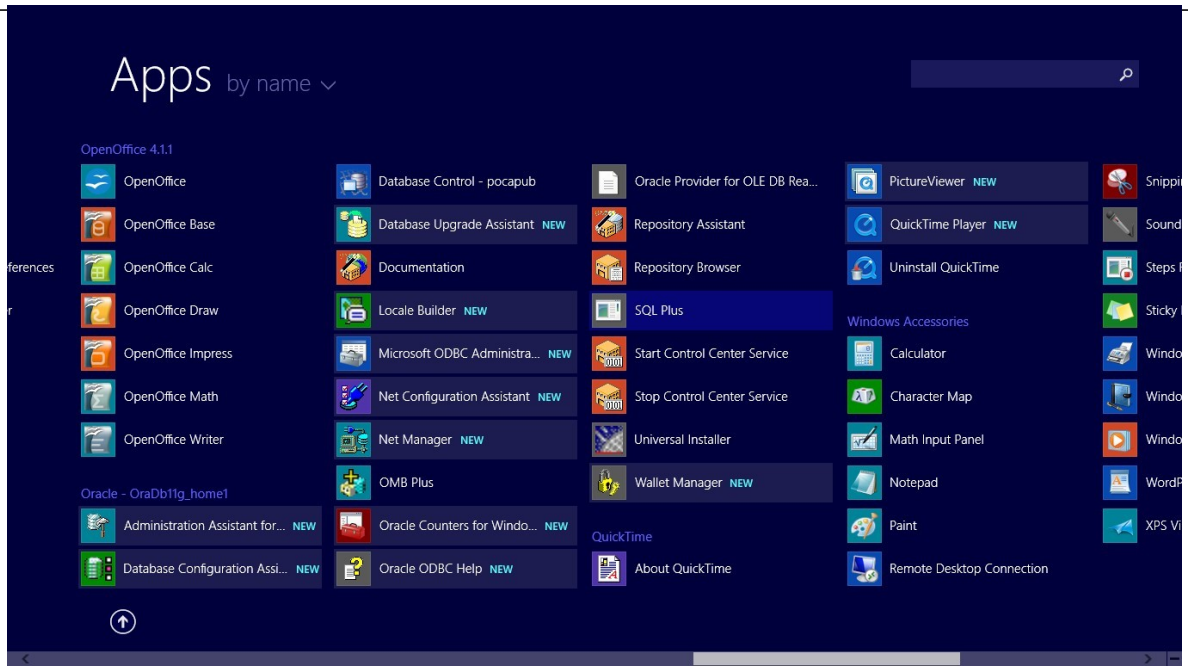
SQL*Plus is a command-line Oracle tool for connecting to Oracle database:

e. Open SQL* Plus as Select: (start, Oracle- OraDb12c_home, Application Development, and then select SQL PLUS)

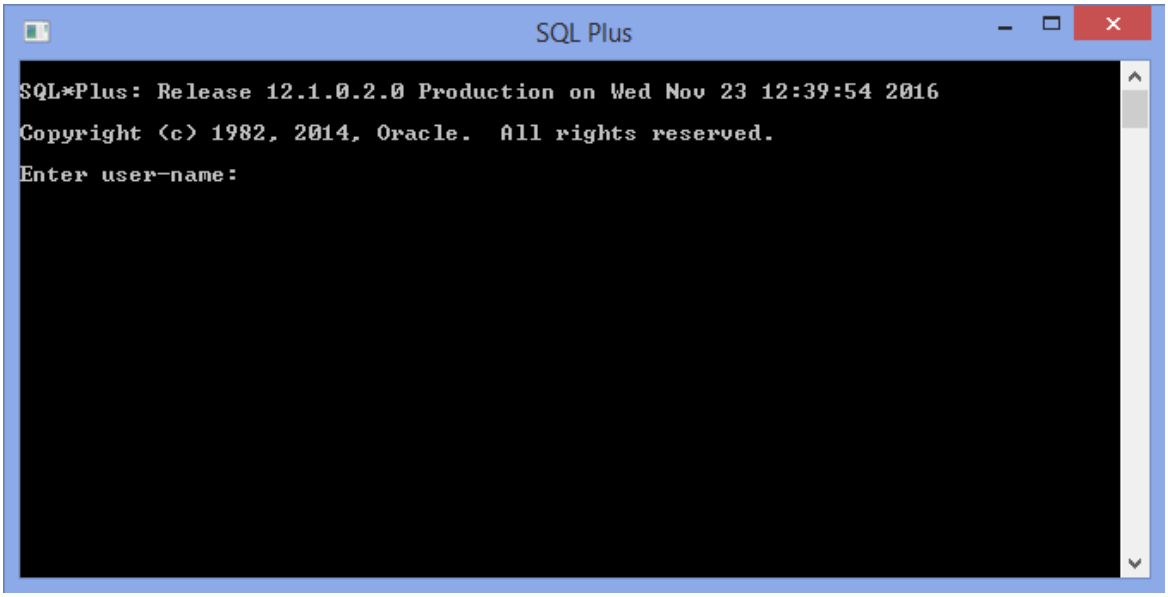
f. The screen below describes how to open SQL*Plus in **Windows 7** or in **Windows 10**



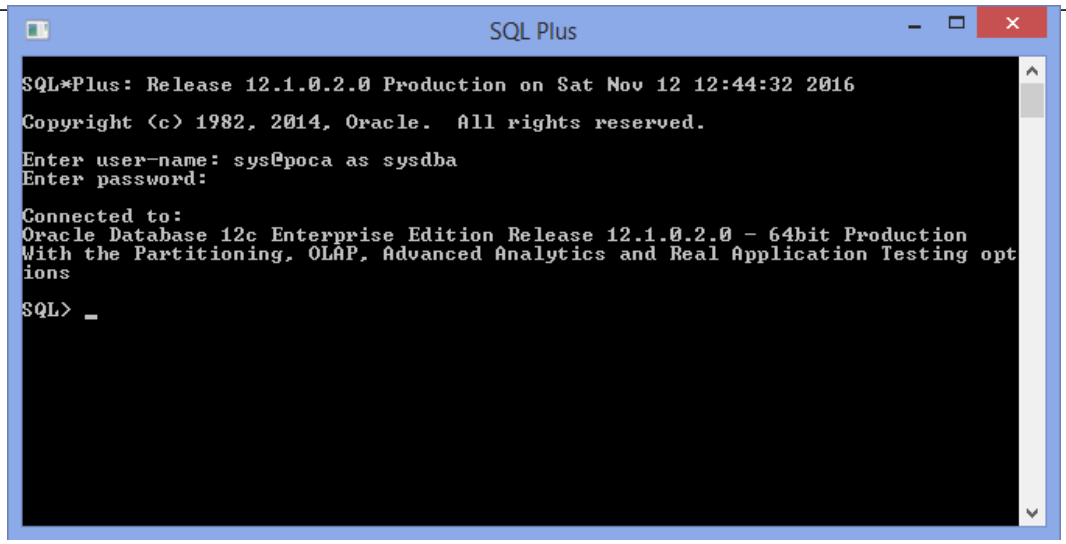
In case of **Windows 8** you need to start from the screen below: Click on SQL Plus.



g. The SQL*Plus window will appear as below.



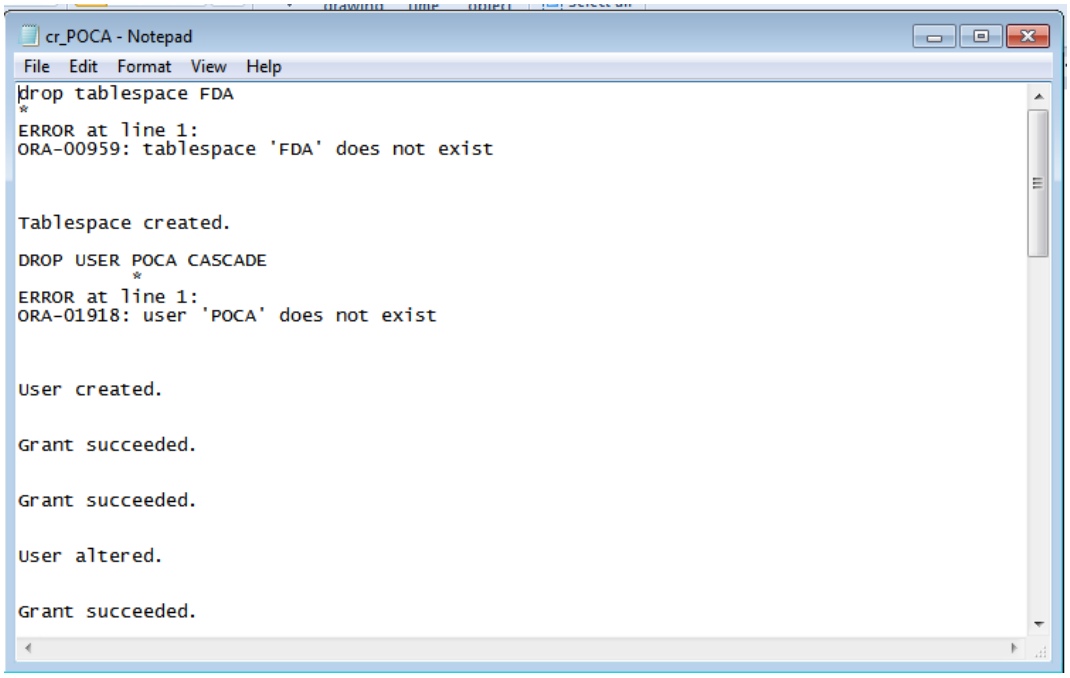
h. In SQL*Plus connect to the poca database with the super user ‘SYS’ as ‘sys@poca as sysdba’. Press ‘Enter’ key and put the Password you created in Sec 3.2 step #9 earlier. It will go to the SQL command prompt.



i. In SQL*Plus (while connected to poca database as user sys) in SQL prompt type as below.

SQL> @C:\POCA_DB_Install\full\create_POCA.sql j. Press ENTER key

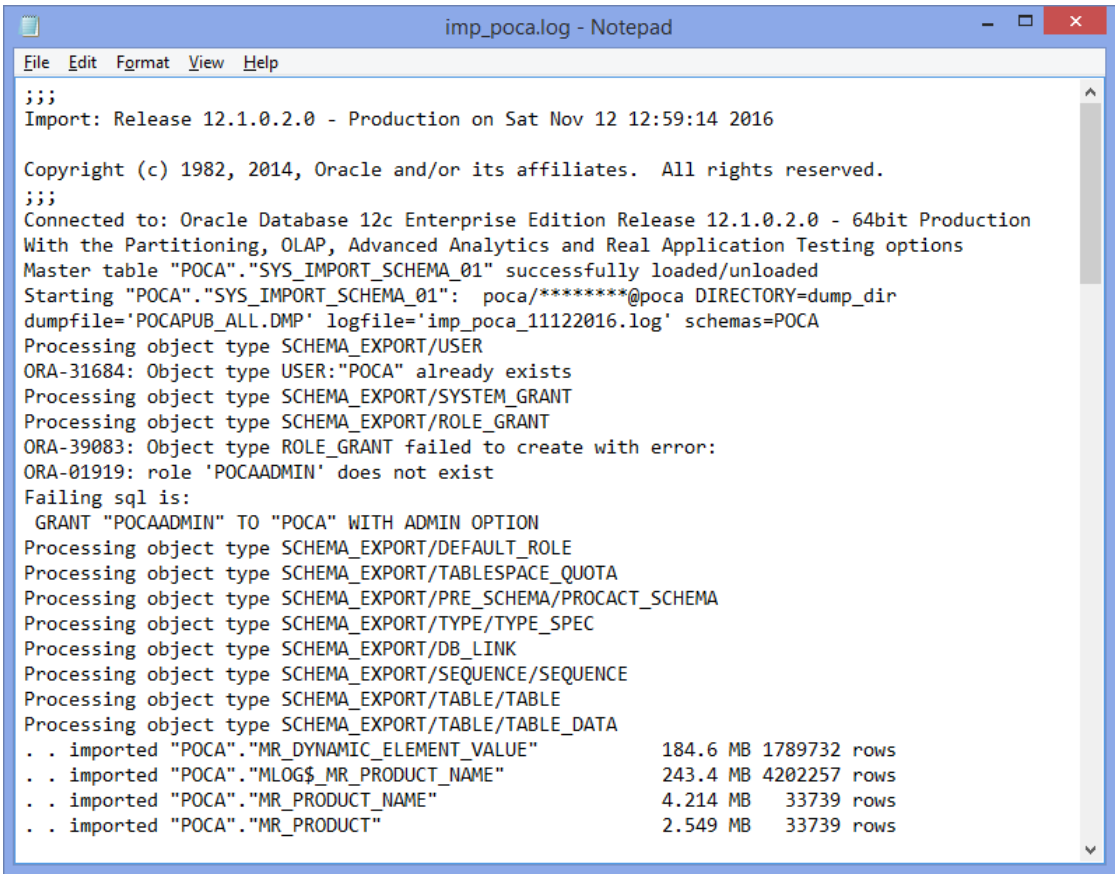
k. Review the **cr**_POCA.log file created in C:\POCA_DB_Install\full folder for errors through NOTEPAD. If you see the ERROR as per screen below, please ignore those errors.



NOTE: If you encounter ORA-65096 error, please refer to the section 5: Additional Notes

Import POCA database

4. Review the import_poca.log file created by default in the C:\dump_dir directory for errors. Open the file import_poca.log in NOTEPAD. The sample log file content is below. At the end it should tell as for example “Job “POCA.SYS_IMPORT_SCHEMA_01” completed…”.



5. If the data load directory poca_data_import is created in different drive than C drive then do the following otherwise skip to next step 8.

   Please change the path name of “u_setting_value”. Open SQL*Plus and connect with “poca” user as poca/poca_user@poca

   SQL> UPDATE poca.user_setting set u_setting_value = 'c:\poca_data_import' where i_setting_id = 4084 and ui_user_uid = '01';
   (Then ENTER)

   SQL> COMMIT;
   (Then ENTER)

6. In SQL*Plus as the user “poca” run the following SQL commands substituting your email address in the line “set u_setting_value = ‘youremail@company.domain’. Use a valid administrator email address to replace ‘youremail@company.domain’ .

```
SQL> UPDATE POCA.user_setting
      SET u_setting_value = 'youremail@company.domain'
      WHERE i_setting_id in (4060,4061,4083);
(Then ENTER)


SQL> UPDATE POCA.users
      SET u_email = 'youremail@company.domain'
      WHERE u_username = 'Admin' ;
(Then ENTER)

SQL> commit;
(Then ENTER)
```

7. In SQL*Plus as the user POCA run the following SQL commands

```
SQL> UPDATE "POCA"."USERS" SET DT_LAST_LOGON =sysdate, I_LOGON_COUNT = '0',
DT_CREATED =sysdate, DT_UPDATED = sysdate, i_failed_attempts=0,
f_password_expired=0 WHERE U_USERNAME='Admin';

(Then ENTER)

SQL> Delete from POCA.USER_PASSWORD_HISTORY;
(Then ENTER)
SQL> commit;
(Then ENTER)
```

Data Load Setup

8. The POCA database includes four data sources, Drugs at FDA, RxNorm, Suffixes in proper name of biological products and United States Adopted Names which will upload upon installation. To upload monthly data refreshes for these data sources, follow the instructions 9 and 10 below.

9. **For future drugs data, FDA will provide formatted data files in the internet site**. You can download data files from there and copy those into 'poca_data_import' directory and the format of the data file names would be as 'rxnorm_YYYYMMDD _New.txt' such as for RxNorm data file and 'drugsatfda_YYYYMMDD_New.txt for DrugsatFDA data file (Example for YYYYMMDD is 20160922 for Sep 22, 2016 is the down load date). After that you can load data through POCA application. Details of data load procedures are described in Help manual.

10. The POCA database creation is complete. Proceed to the next section, "Installing the Application."

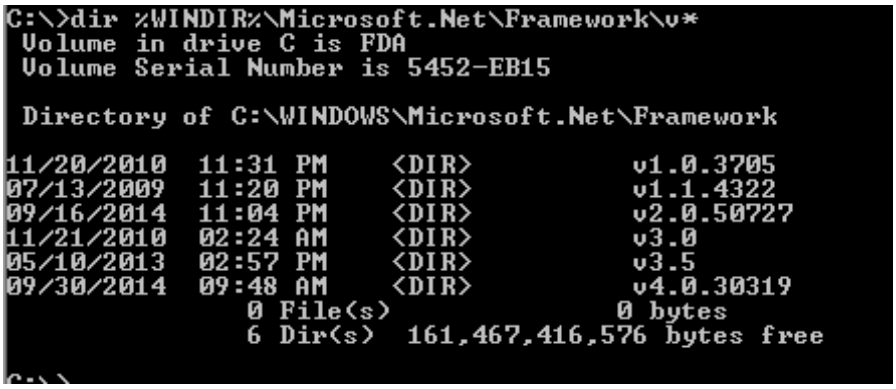
4. INSTALLING THE APPLICATION

Assumptions:

- C:\Inetpub\wwwroot is the default folder for IIS virtual directories
- .Net framework 4.0 is installed

To check which .NET Framework version is installed, run the following from command line.

dir %WINDIR%\Microsoft.Net\Framework\v*



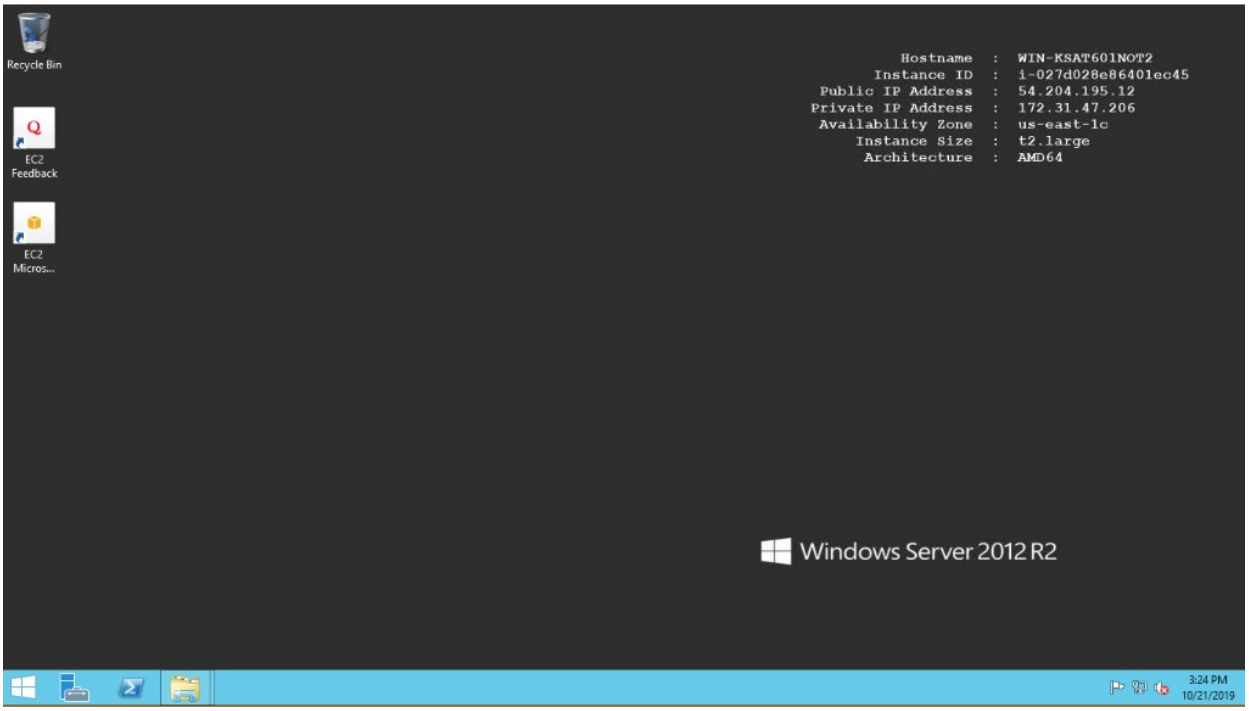
Create a folder 'poca' under C:\Inetpub\wwwroot. On the POCA extracted folder, find the folder "POCA_Published_Files." Copy the contents of the folder into the x:\Inetpub\wwwroot\poca folder on your computer, where x is the drive where IIS is installed (usually C:\).

Next steps are different in Windows Server 2003, Windows Server 2012 and Windows 7/8/10.

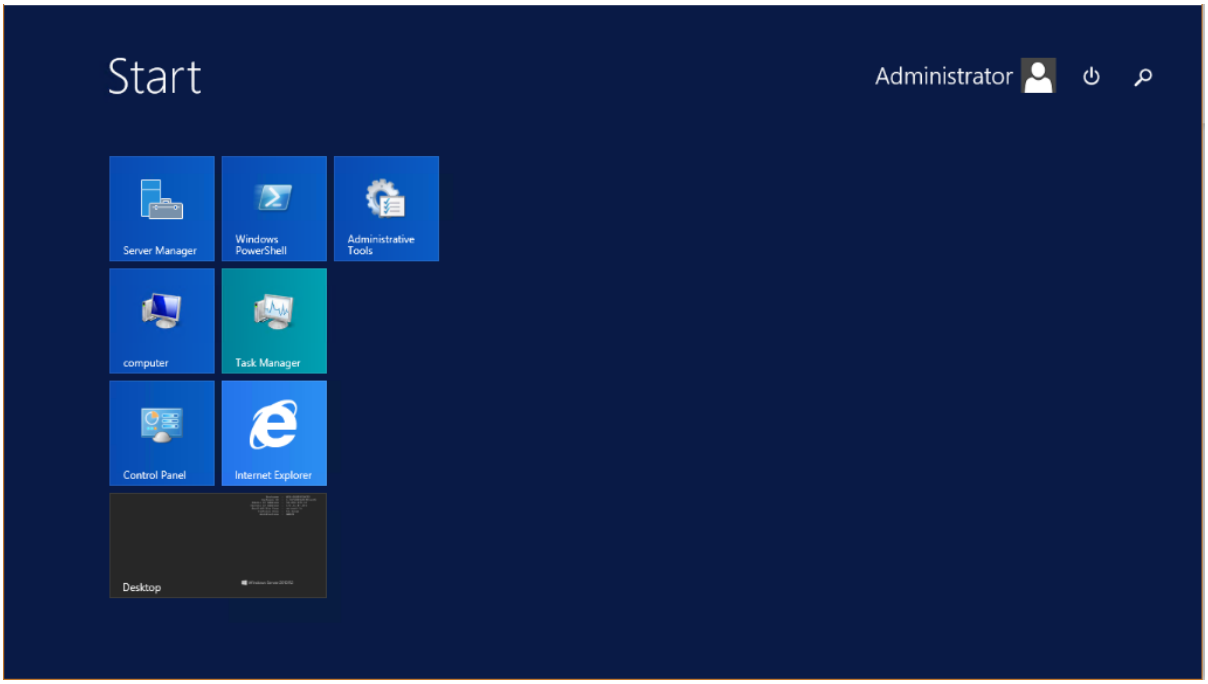
4.1 Installation in Windows Server 2012

1. Install IIS

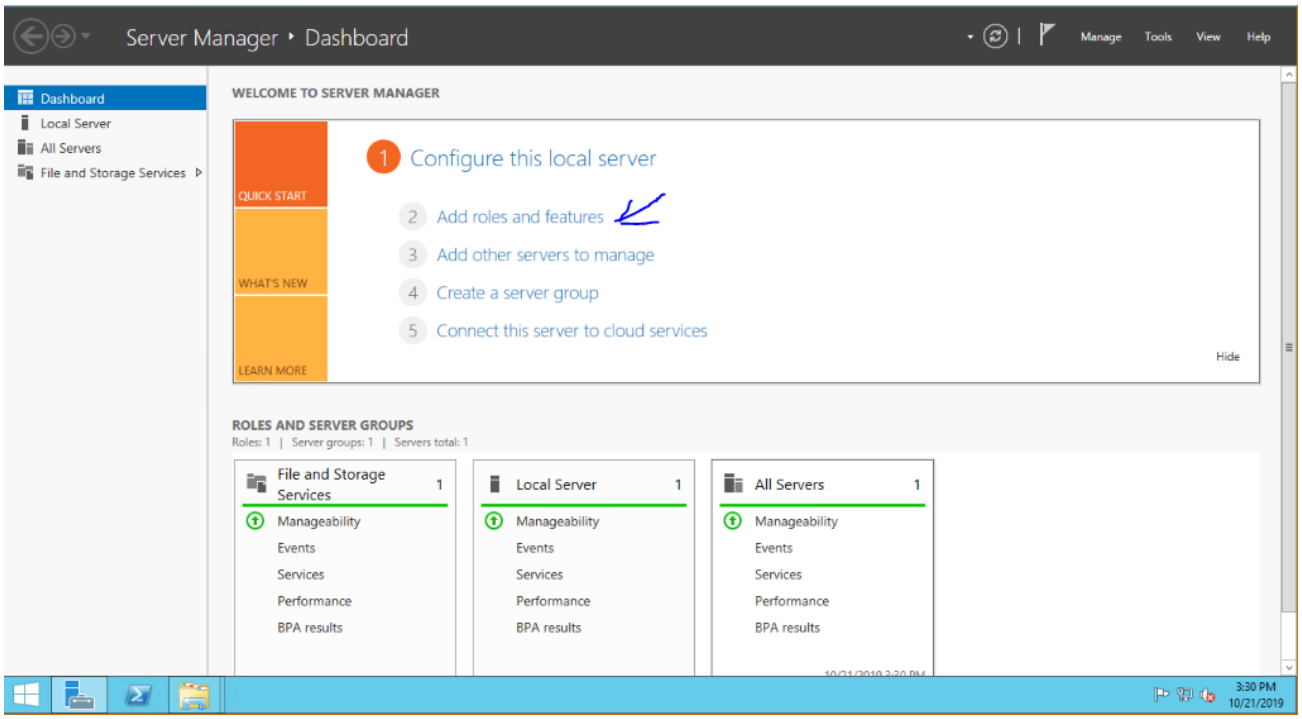
Click on the bottom left Windows button.



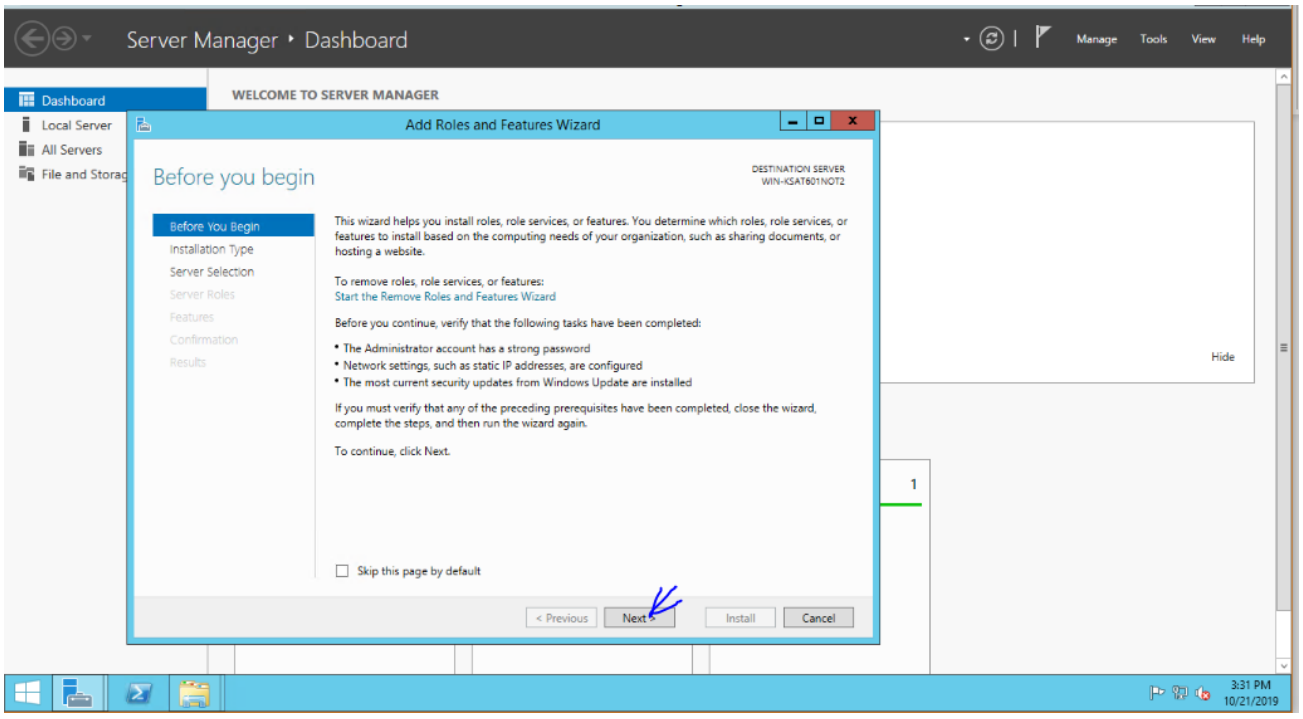
Locate Server Manager and Click



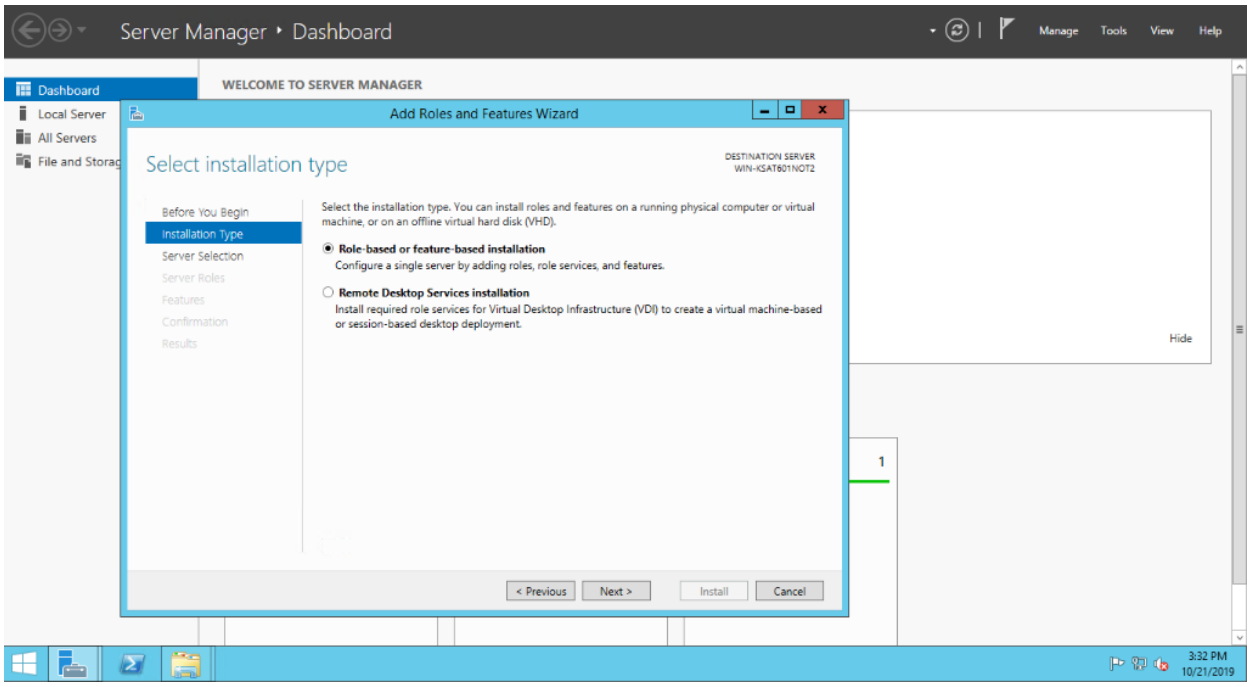
Click on Add roles and features



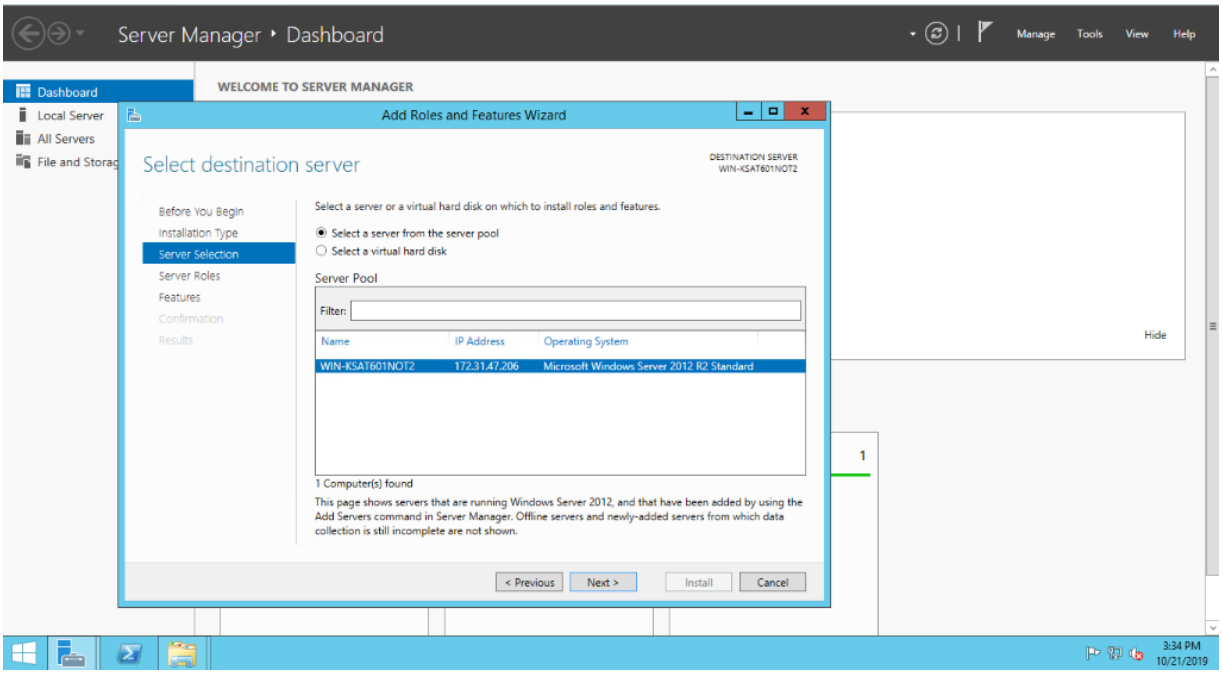
Click Next



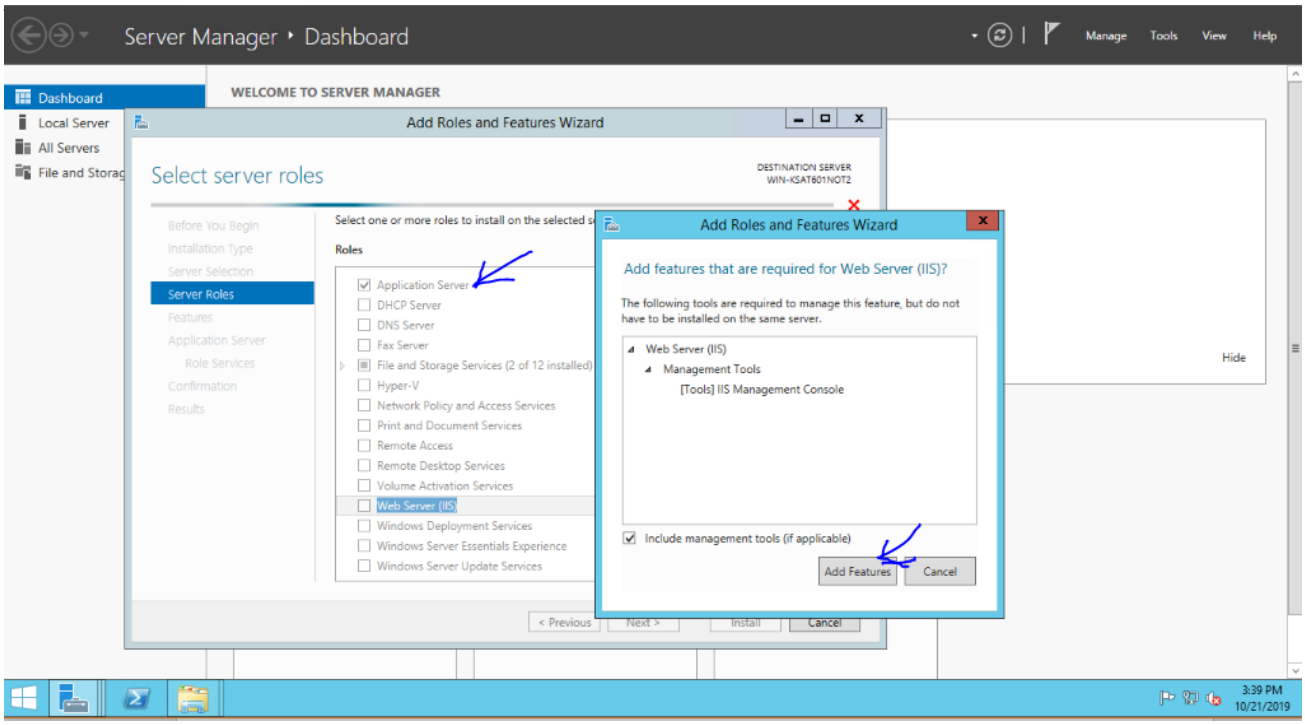
Click Next again.



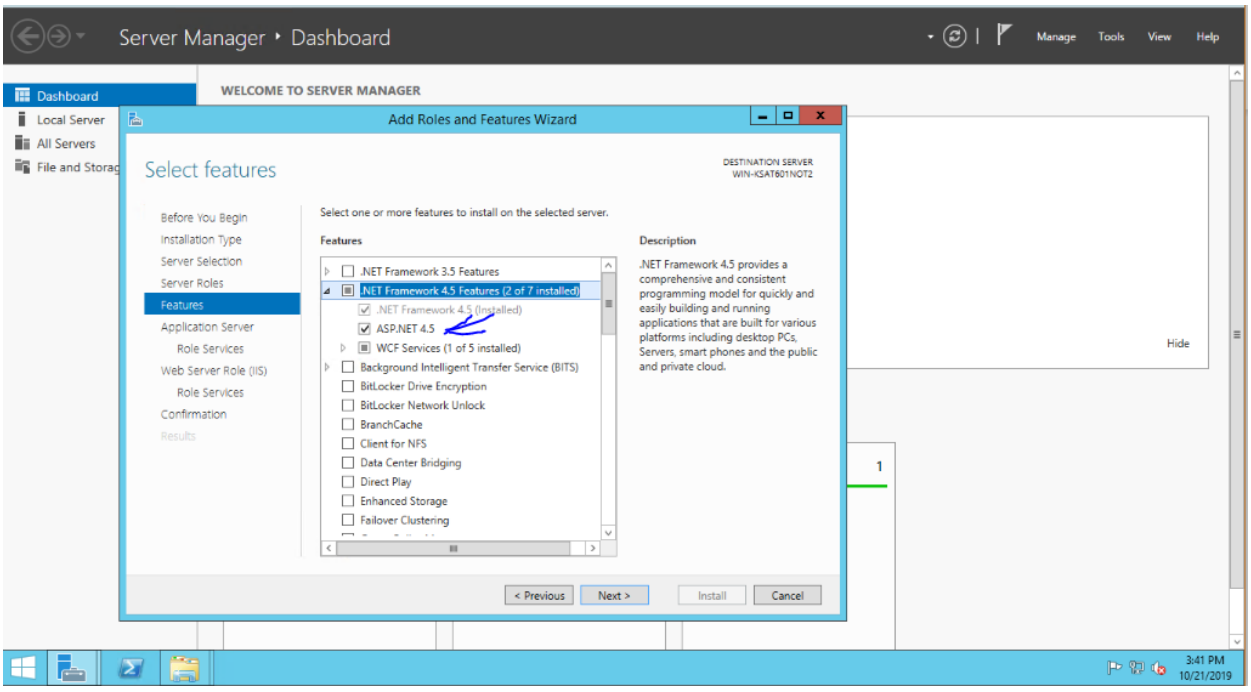
Click Next



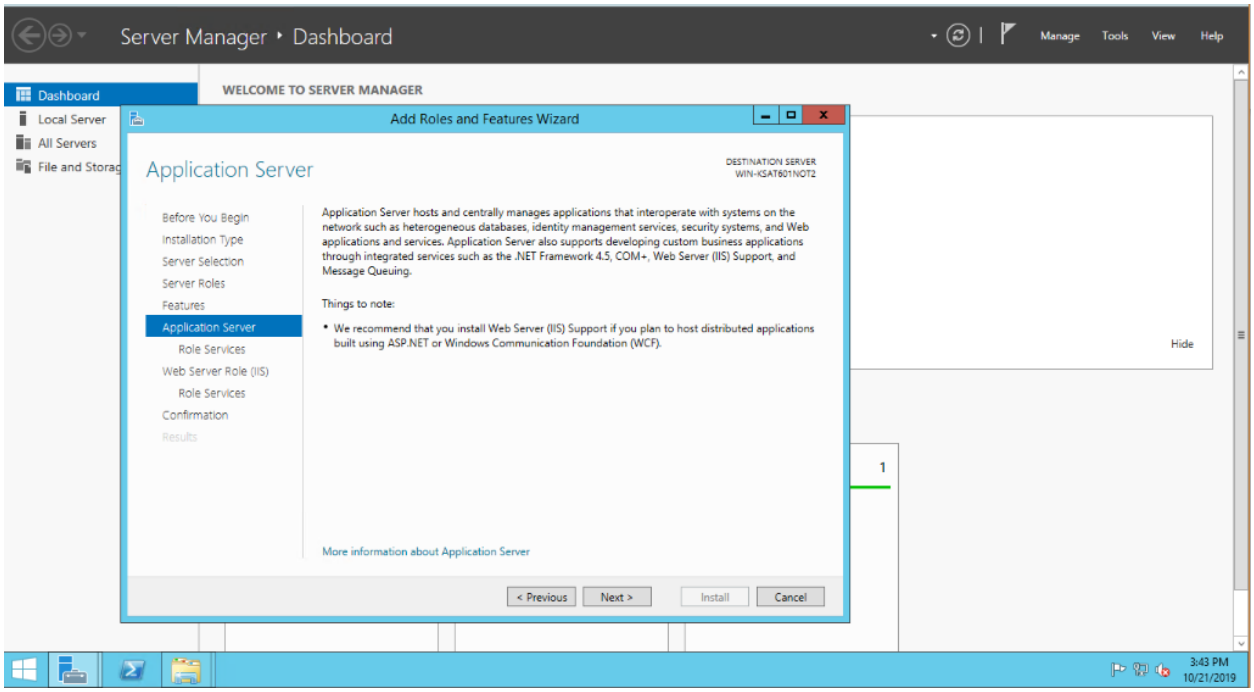
Click Next and Check Application Server and Web Server (IIS).
When you click on Web Server, a popup will show. Click on Add Feature.



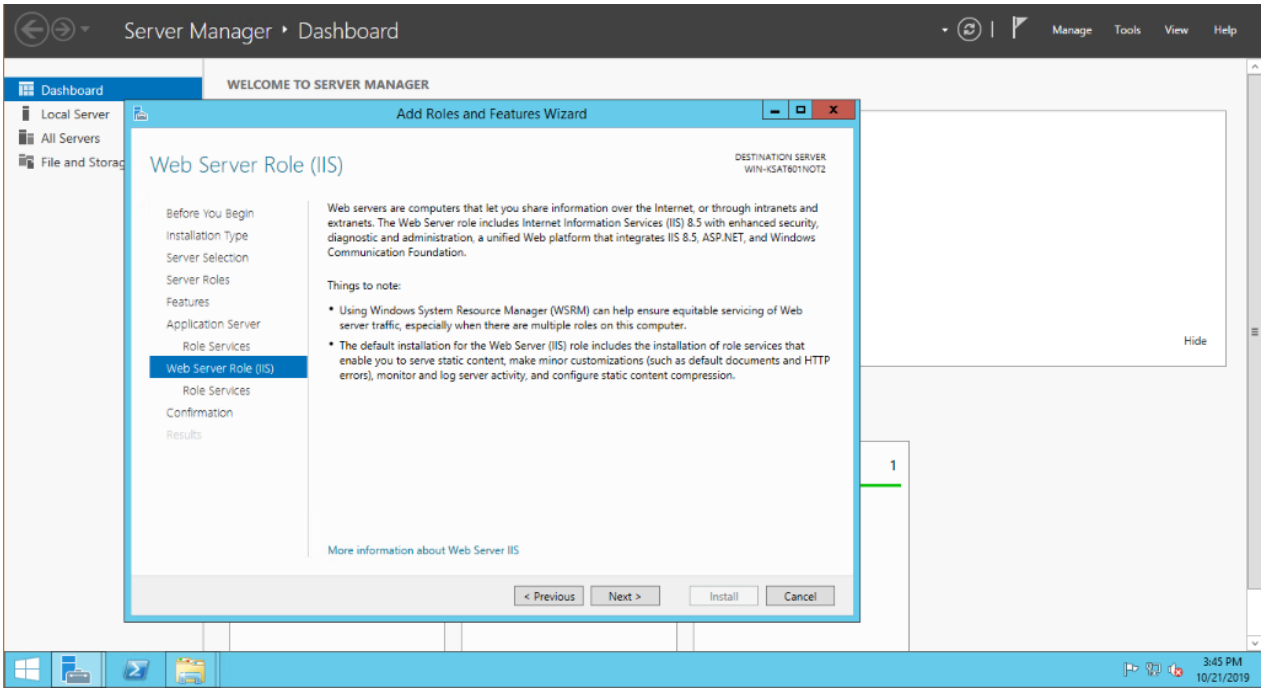
Click Next. Click on .Net Framework 4.5. Make sure ASP.NET is checked.



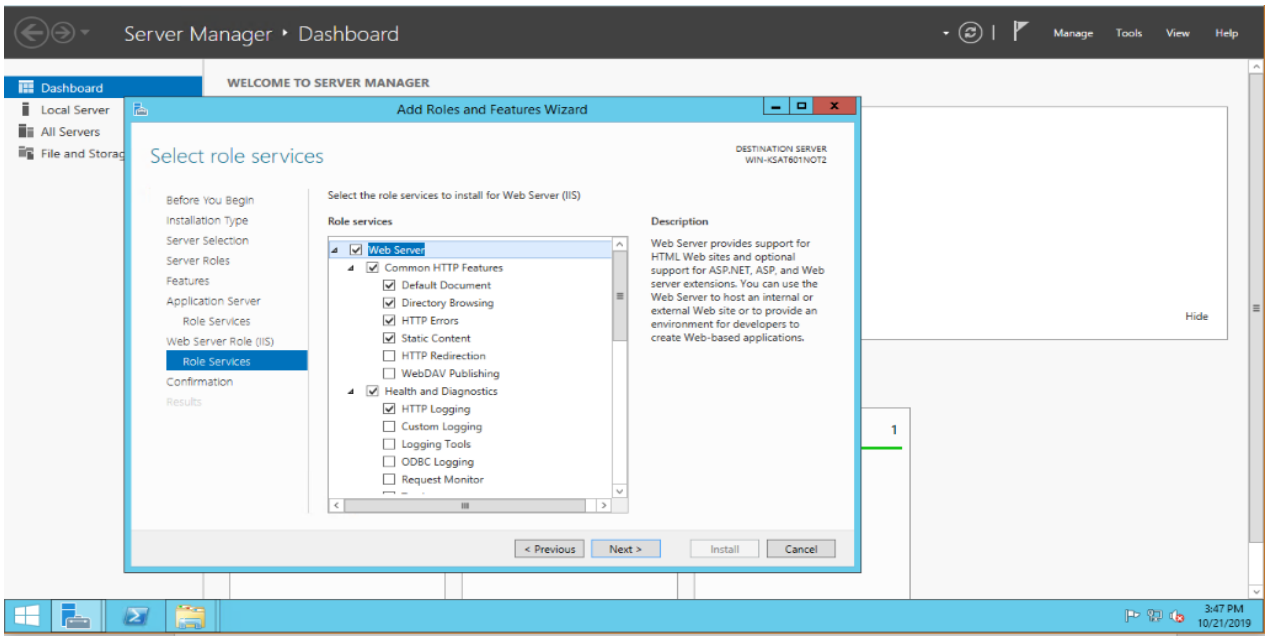
Click Next



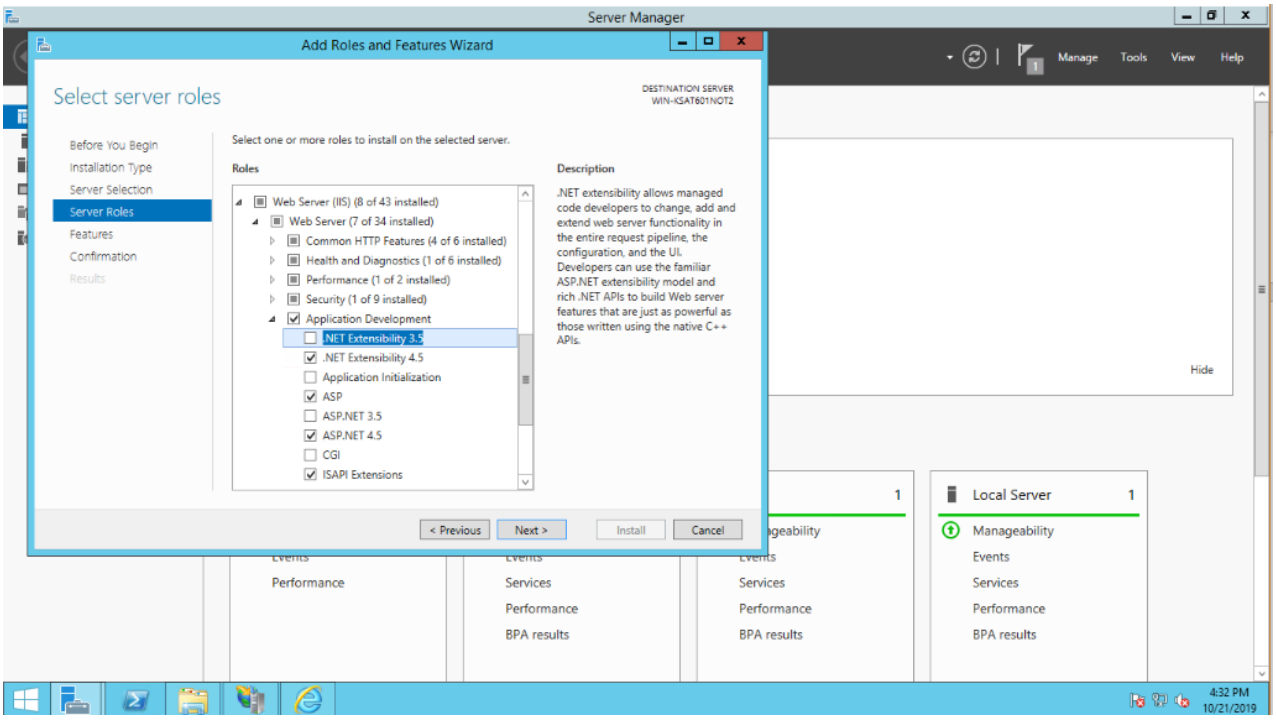
Click Next



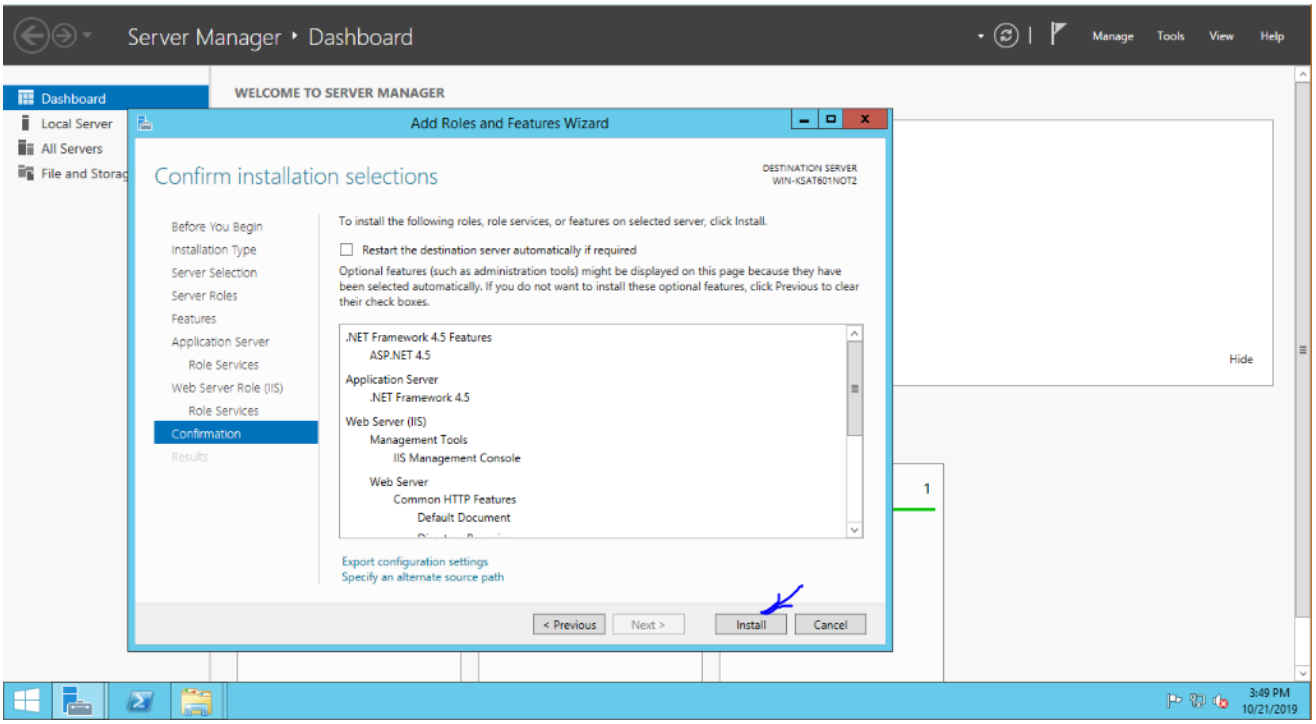
Check Web Server as below.



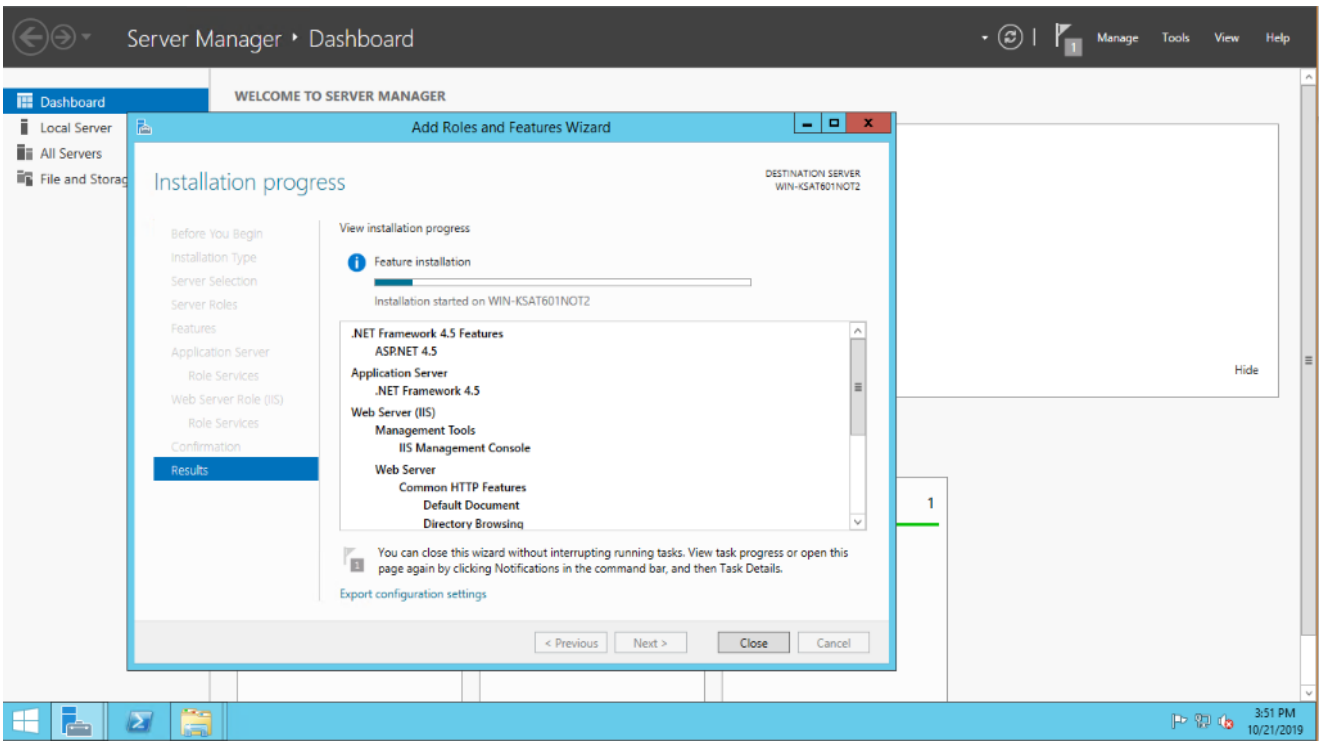
Scroll down and select .Net options as below



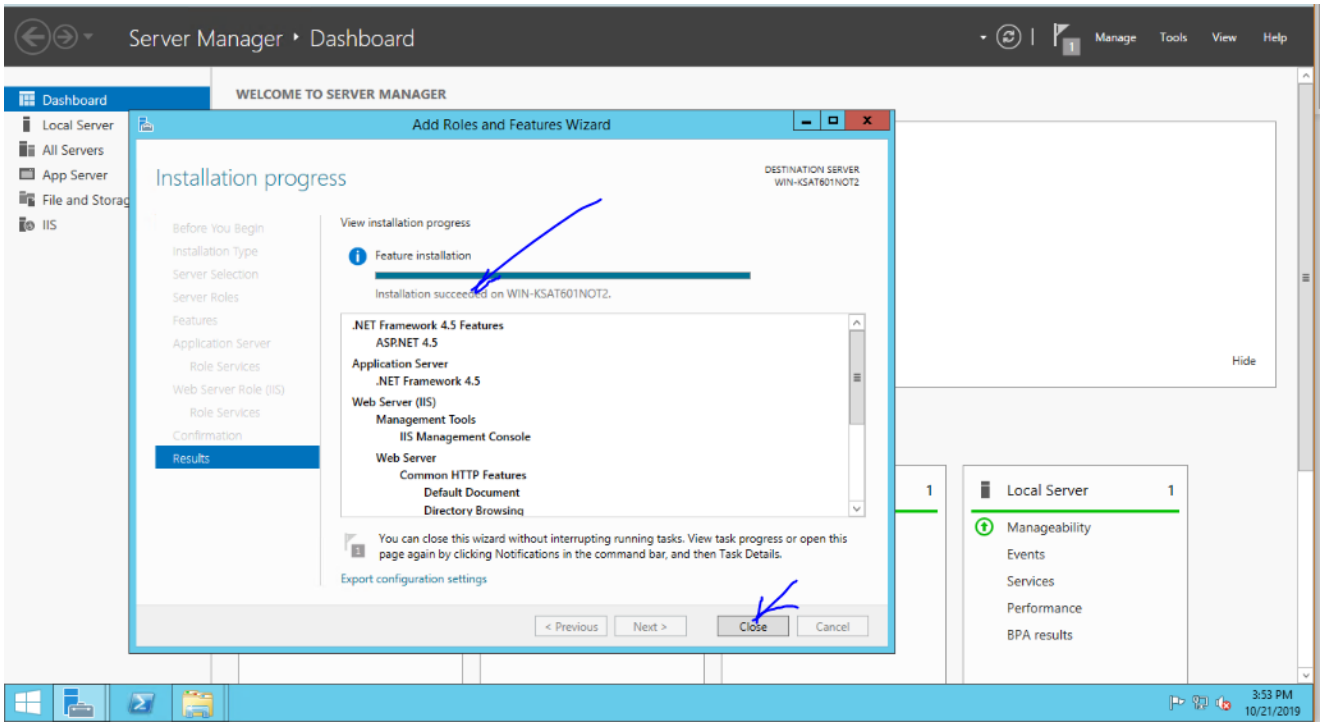
Click Next and Verify the roles and features and click Install.



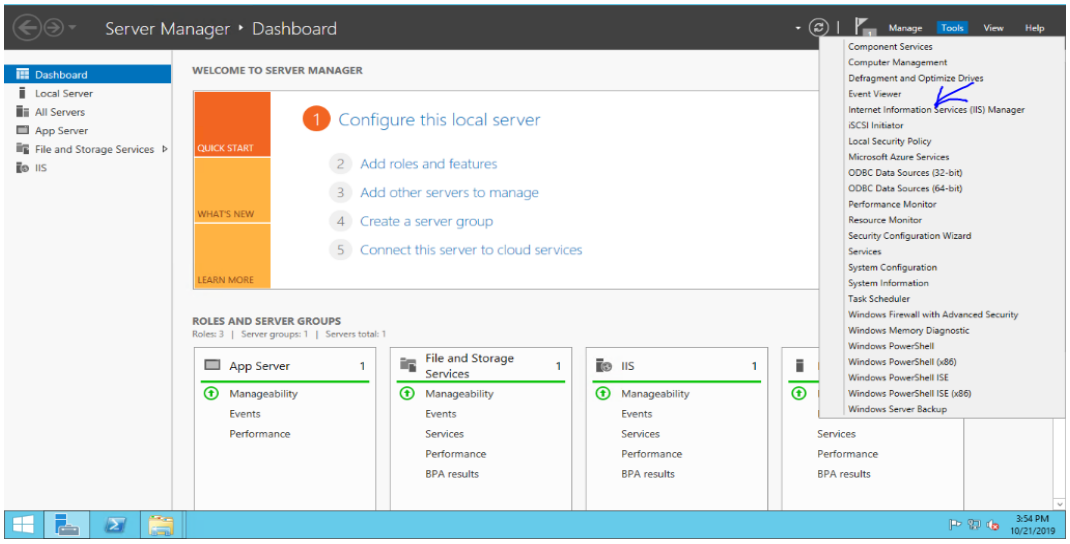
Monitor the progress.



Click Close after Install is successful.



Verify that IIS is installed and click on IIS Manager.



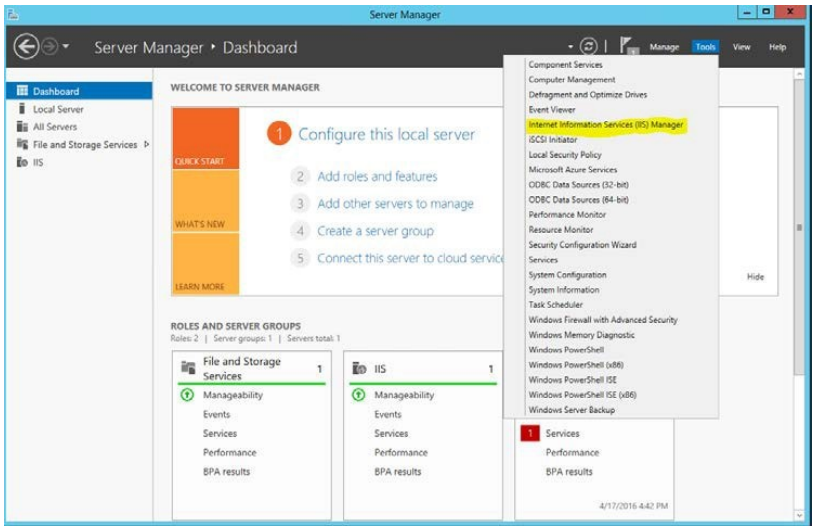
Before next steps, make sure you have performed the following, if this is a fresh install of Application. In case the application is being upgraded from 4.2 to 4.3, you should already have the POCA folder in IIS root.

In case of Fresh install –

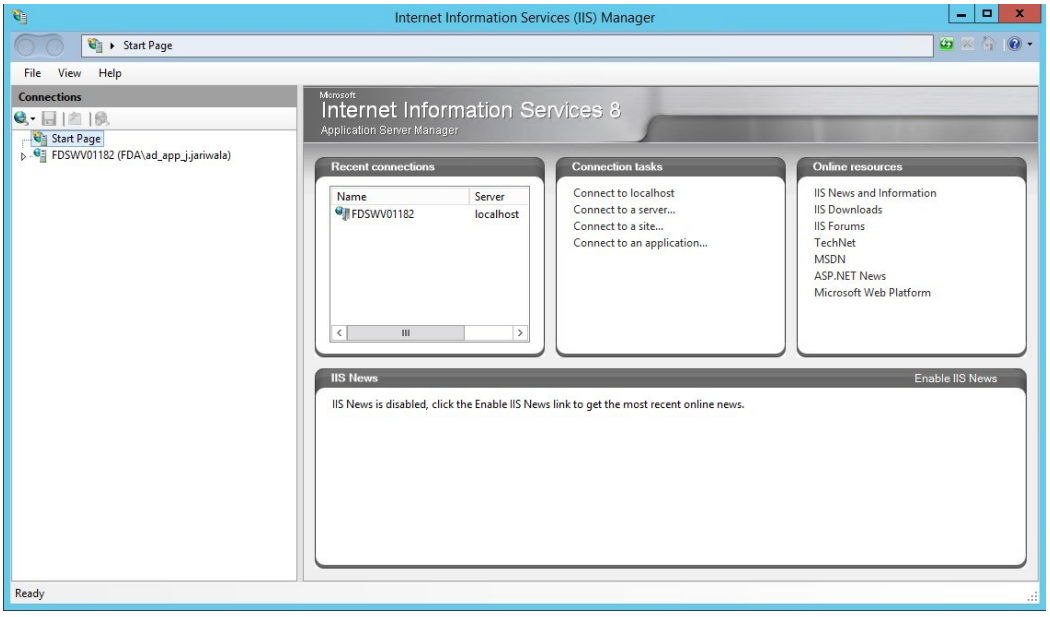
- Create a folder ‘poca’ under x:\Inetpub\wwwroot.

- On the POCA extracted folder, find the folder "POCA_Published_Files."
- Copy the contents of the folder into the x:\Inetpub\wwwroot\poca folder on your computer, where x is the drive where IIS is installed (usually C:\).

2. Open Internet Information Services Manager (Start->All Programs->Administrative Tools->Internet Information Services Manager) Or
In the **Server Manager** Window, click on **Tools** menu and then **Internet Information Services (IIS) Manager** as shown in screen below.

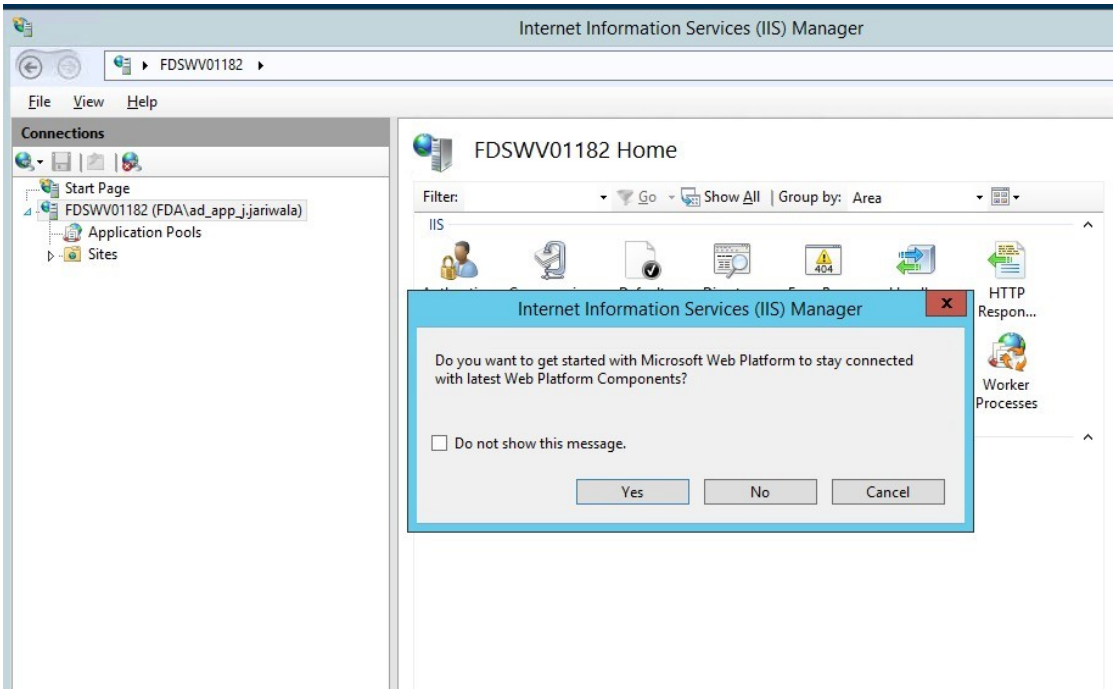


3. The **Internet Information Services (IIS) Manager** window will open.

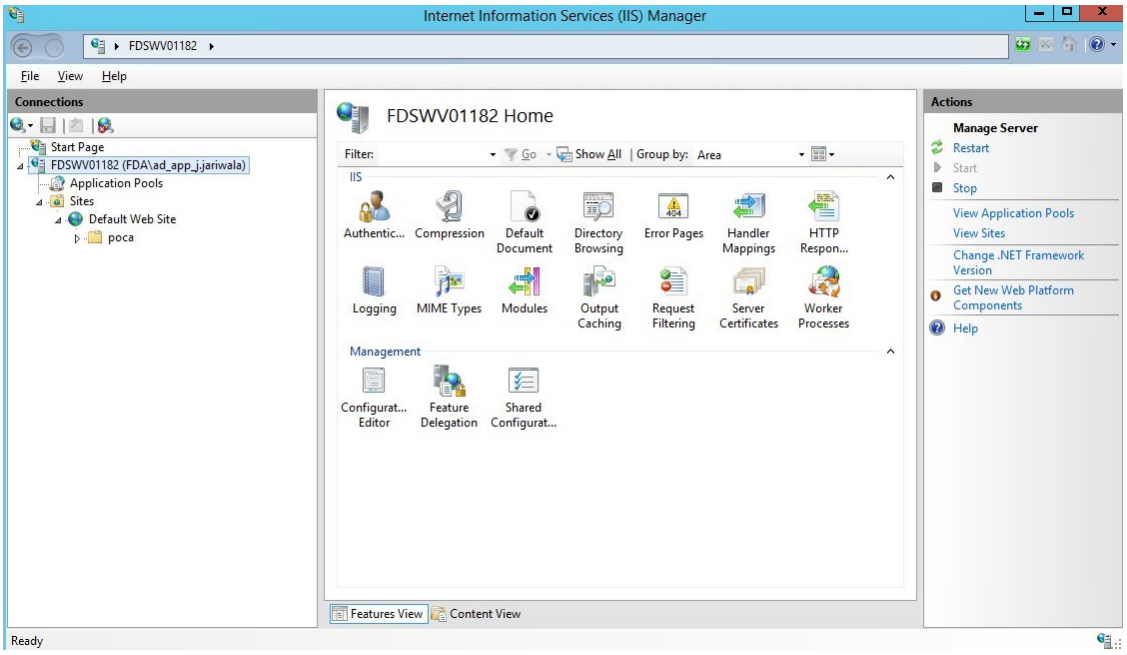


4. Expand the **server name** in IIS Window. If applicable, Click on the **Do not show this message**

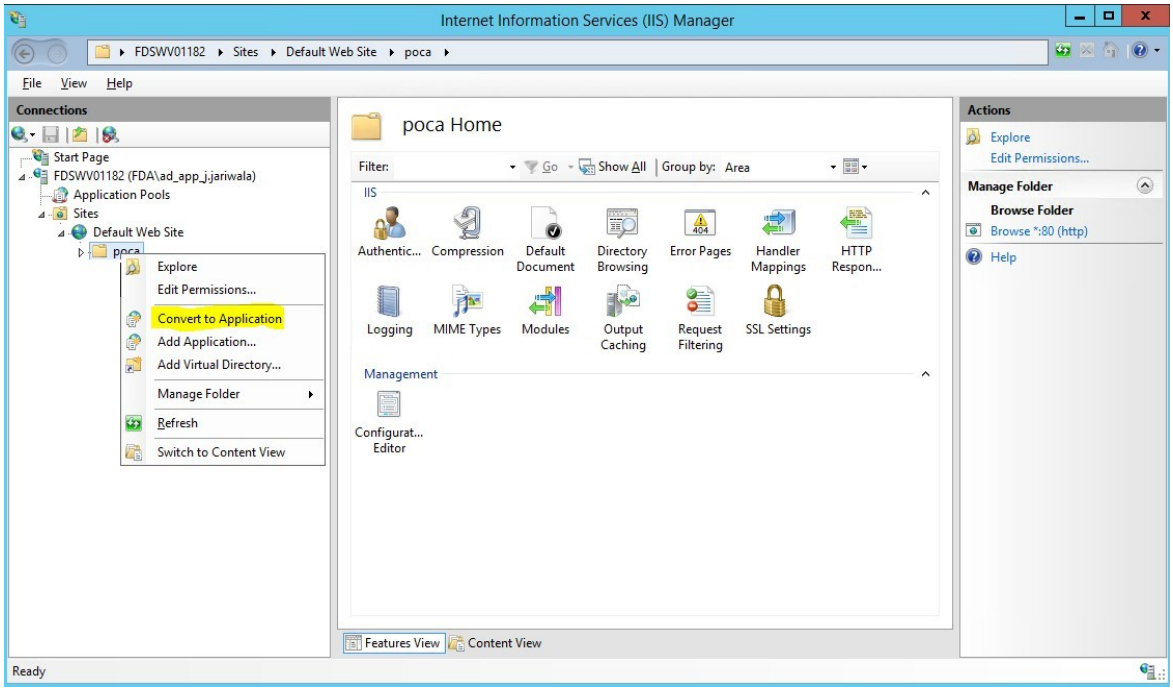
checkbox and Click **No** to "Do you want to get started with Microsoft.." popup. This step may not be needed if this popup don't appear.



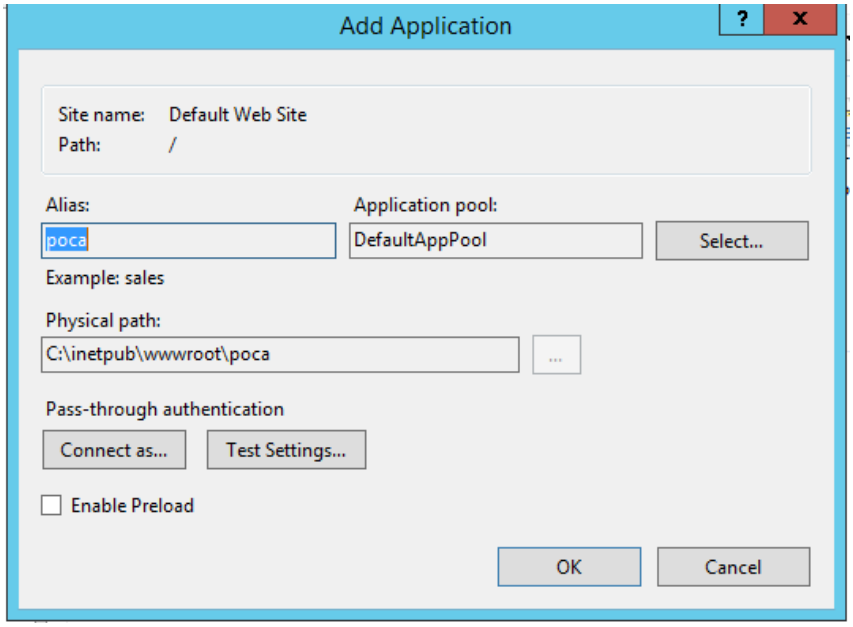
5. Expand **Sites**. Expand **Default Web Site**.



6. Right click on **poca** and select **Convert to Application**.



7. Click **OK** on **Add Application** window.



8. Right click on “Default Web Site” in left pan and click on Refresh menu item to refresh the websites. The poca folder will be refreshed and appear as poca website.

9. Open internet browser and type http://localhost/poca in address bar and press enter. You will see the POCA application page with login page.

Disclaimer
This is a Federal computer system and is the property of the United States Government. It is for authorized use only. Users (authorized or unauthorized) have no explicit or implicit expectation of privacy.

Any or all use of this system and all files on this system may be intercepted, monitored, recorded, copied, audited, inspected, and disclosed to authorized site, Food and Drug Administration, and law enforcement personnel, as well as authorized officials of other agencies, both domestic and foreign. By using this system, the user consents to such interception, monitoring, recording, copying, auditing, inspection, and disclosure at the discretion of authorized site or Food and Drug Administration personnel.

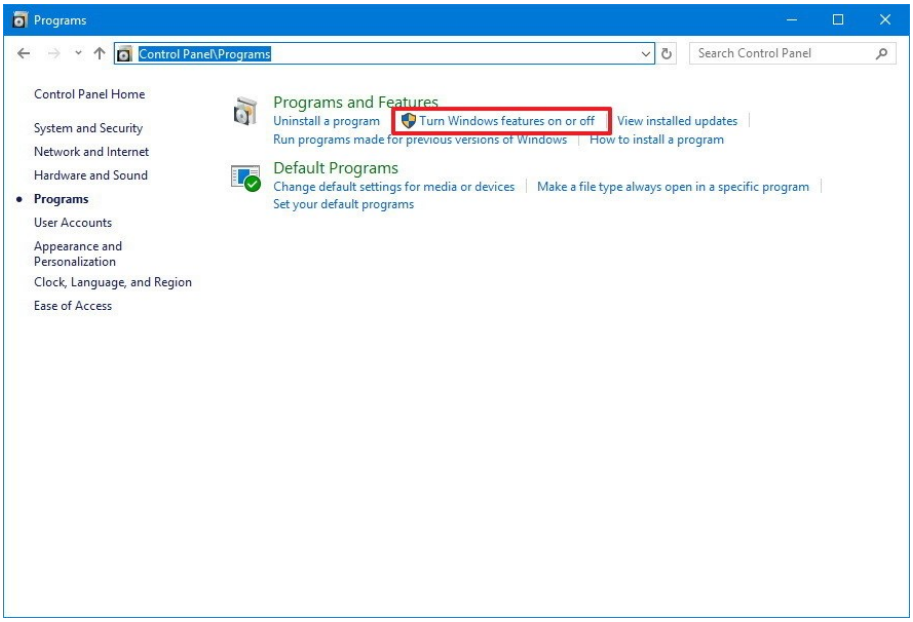
Unauthorized or improper use of this system may result in administrative disciplinary action and civil and criminal penalties. By using this system you indicate your awareness of and consent to these terms and conditions of use.

10. Log into the application with the User ID “Admin” and password “pocaadmin$.”

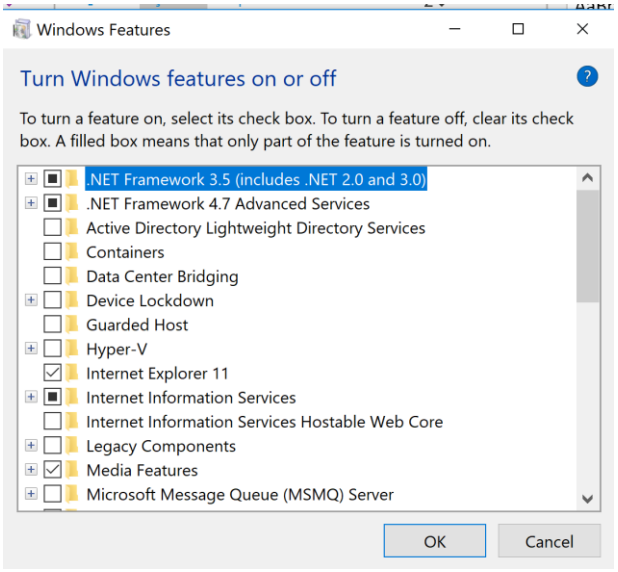
4.2 Installation in Windows 7I Windows 8 I Windows 10

Before configuration of **Internet Information Services**, you need to turn on some optional features on Windows 10 using Control Panel:

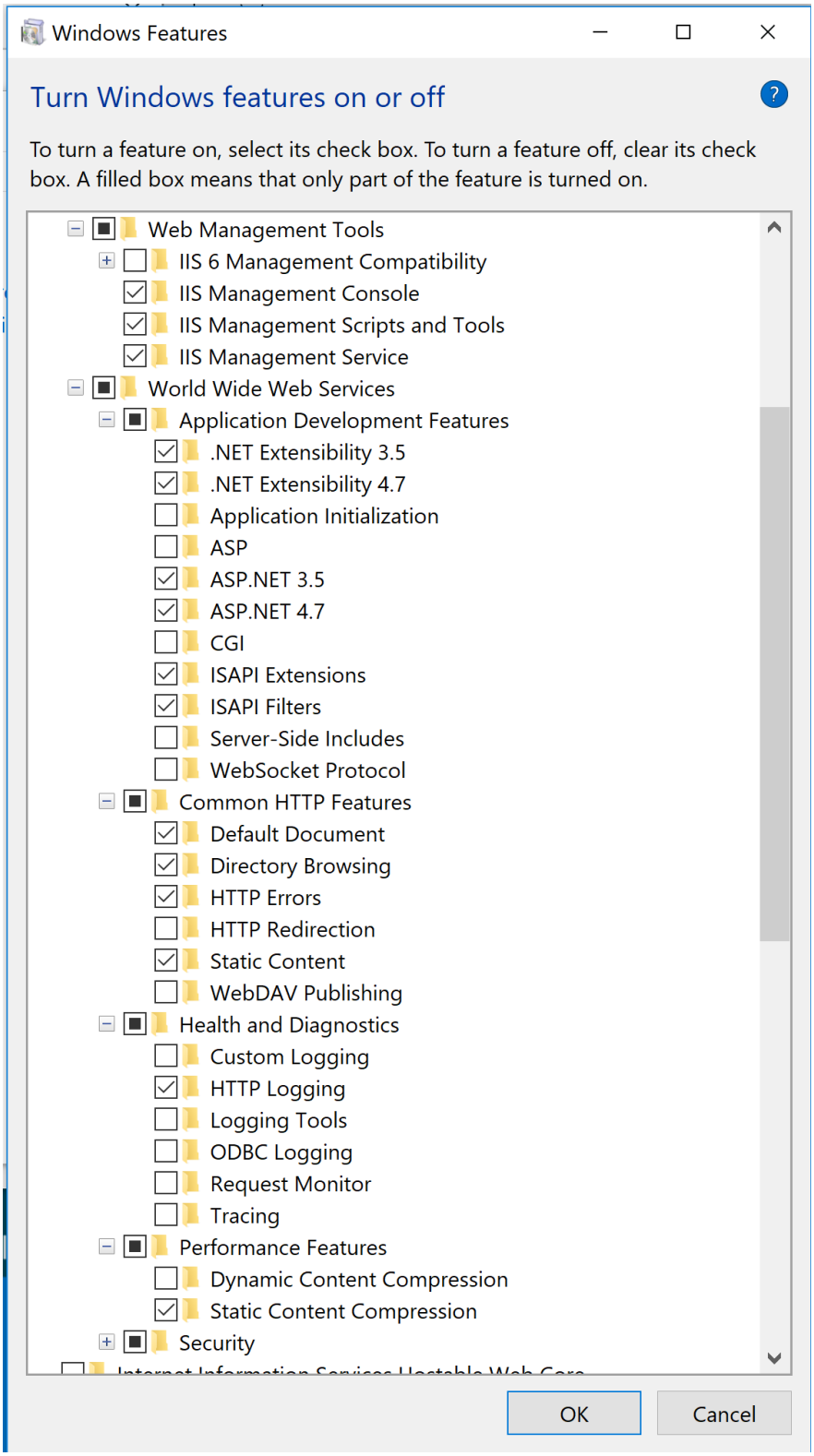
a) Open **Control Panel**.
b) Click on **Programs**.
c) Click the **Turn Windows features on or off** link.



d) On Windows Features, check or clear the features you want.

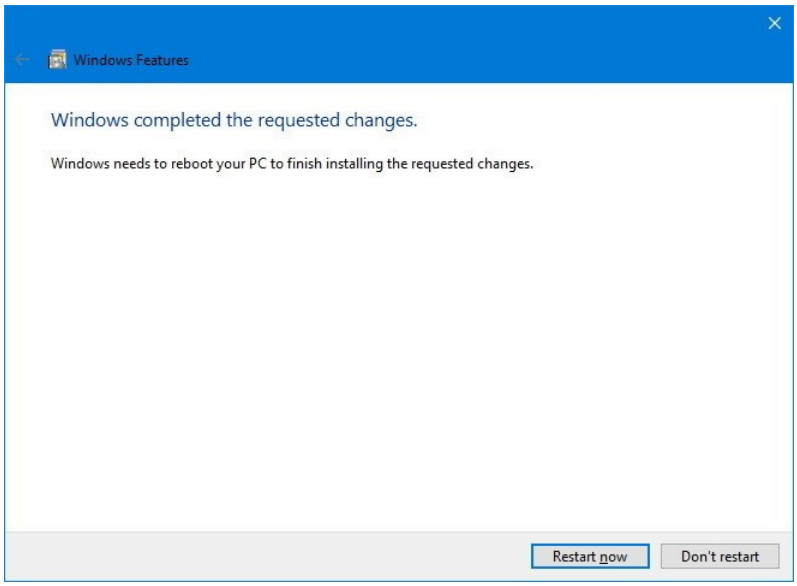


e) Select “Web Management Tools” and the selected features as below of “ World Wide Web services”.

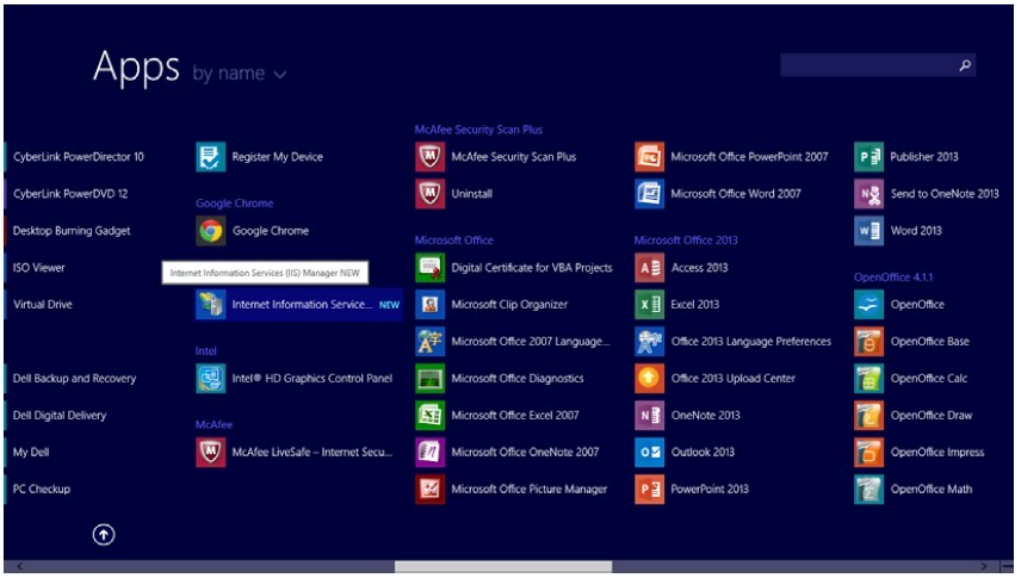


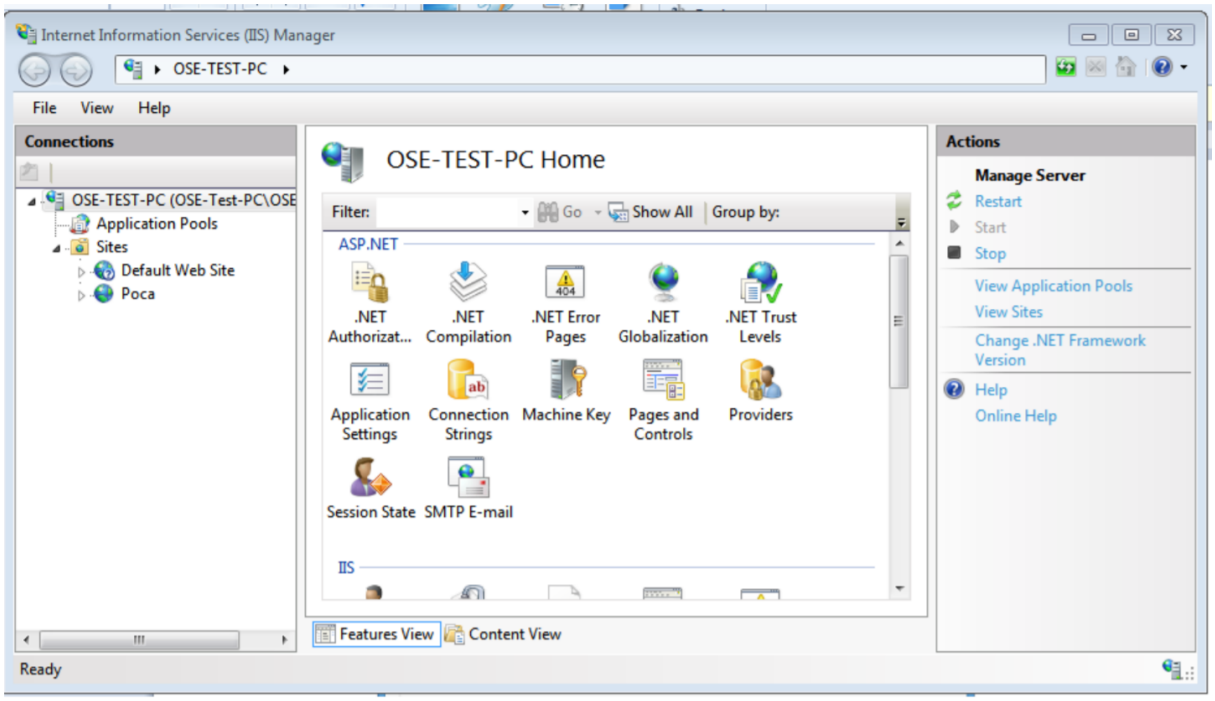
f) Click **OK** to enable the feature.

g) Restart your computer as indicated by the wizard to complete the task.

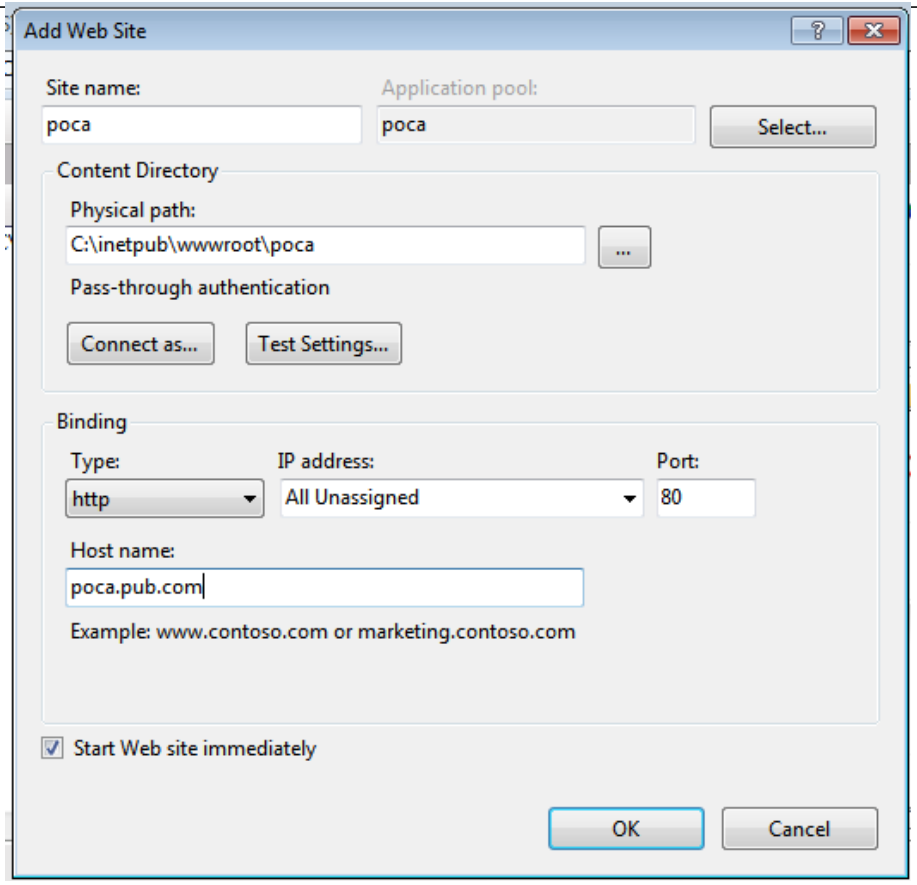


1. Open IIS Manager by putting ‘iis’ on the ‘search program and files’ after Windows Start menu for Windows 7 or Windows10. IIS Manager can be started in Windows 8 as below

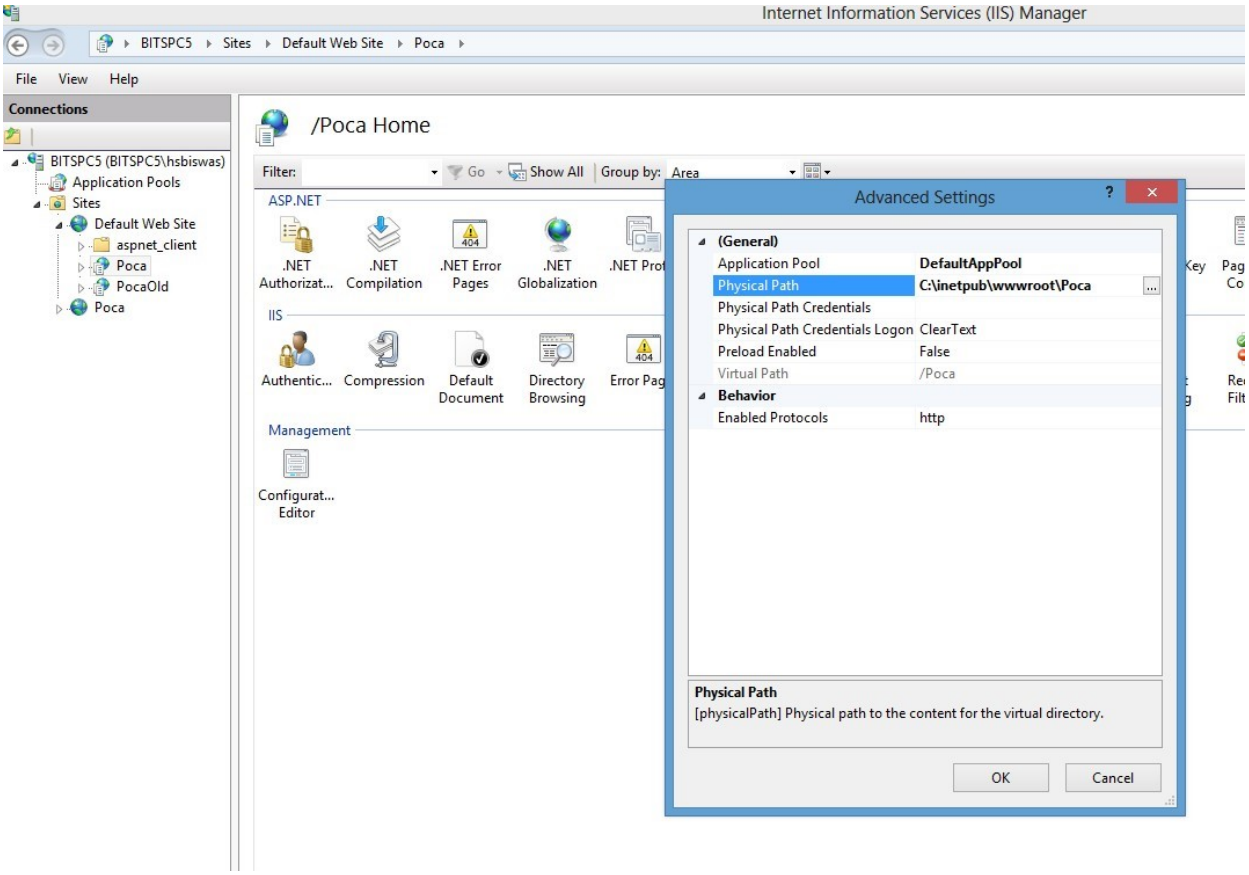




2. Right click on “Sites” in the left menu and click on Add web site. Fill up the configurations as below



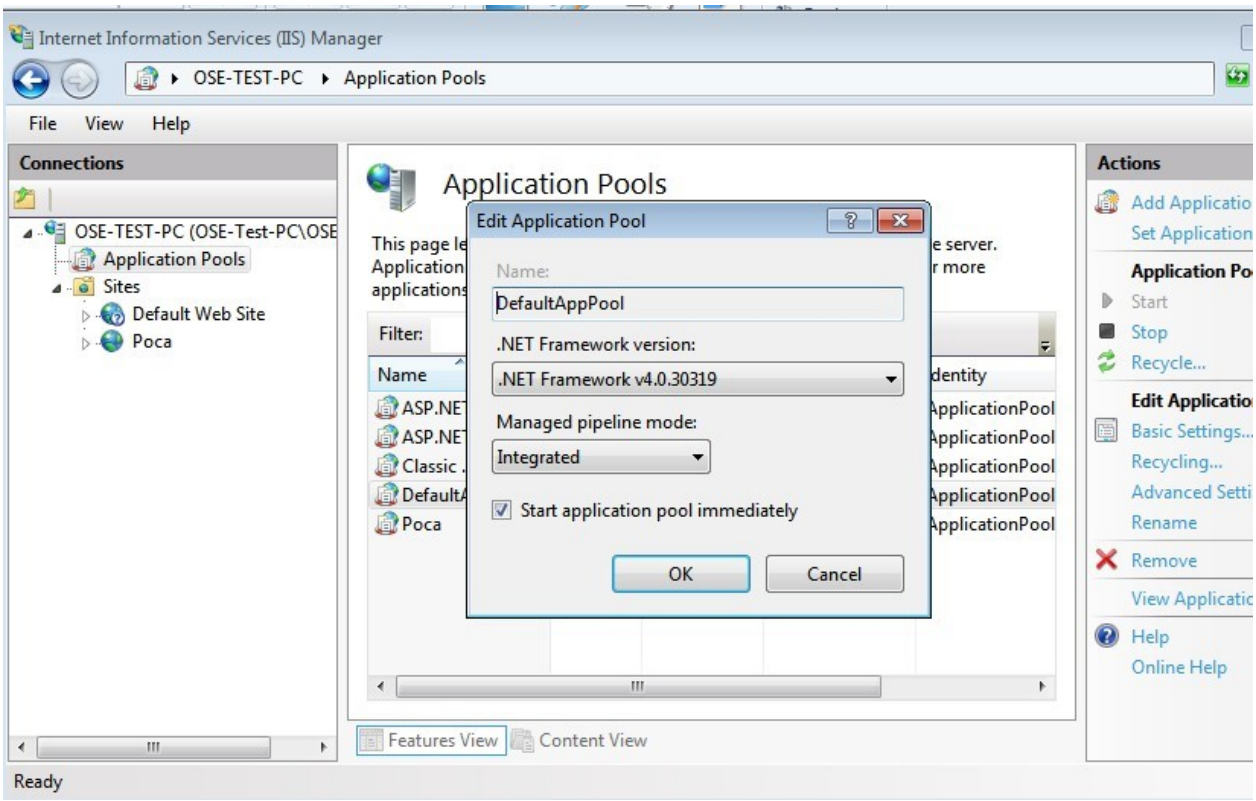
3. Expand “Sites” and you will find “poca” under there. Click on Poca folder and click on Advanced Settings in the right pane.



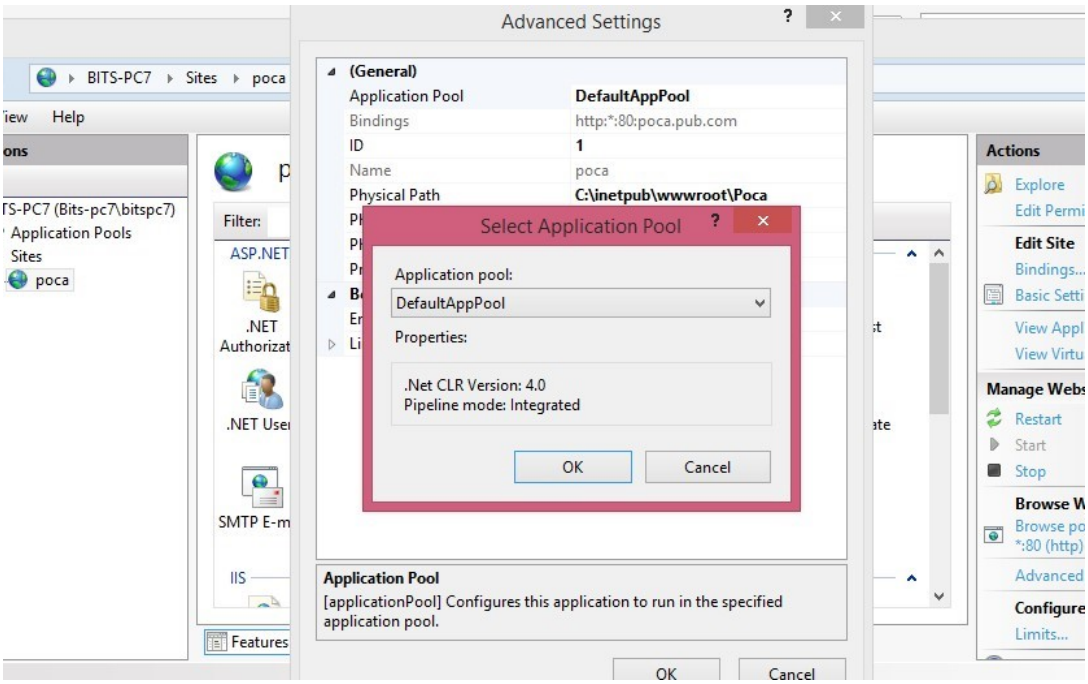
.

4. **The Application pool is the DefaultAppPool.** Check the properties of DefaultApplication pool. .NET Framework should be 4.0 and run under classic or integrated pipeline

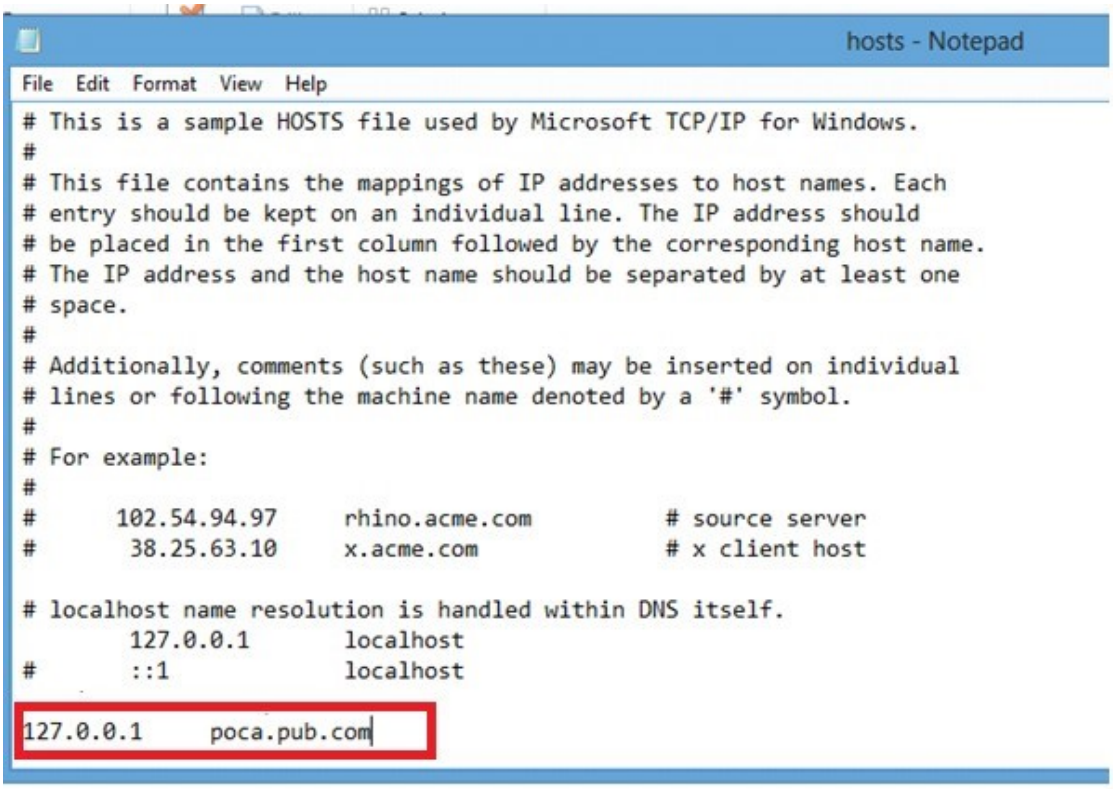
The following screen print will appear for Windows 7/Windows 10 IIS.



Same screen for Windows 8 IIS will be little different as below:



5. There is a host name entry for the application during the creation of Web site through IIS Manager. Your host name is poca.pub.com and hosts file is located at C:\Windows\System32\Drivers\etc. Enter the new host as below. The Administrator privilege is required to modify the hosts file. Open NOTEPAD as Administrator and open the file on there. Add the new entry at the bottom as below.



6. **Web.config** file under c:/inetpub/wwwroot/poca folder needs to be configured. Based on EmailServerType the values need to modify. If the corporate SMTP server is used, then 'EmailServerType' will be 'Custom' otherwise 'gmail' can be used for any publicly open email server. **In publicly open email server DO NOT CHANGE '<add key="EmailServerType" value = "gmail" />'**. If you want to use different email servers other than Gmail e.g. Hotmail, Yahoo etc., just change the other variables like EmailServer, EmailUsername, EmailUserpassword, EmailPort and EmailEnableSSL accordingly. In that case, you can replace the value of the variables 'EmailUsername' and 'EmailUserpassword' with your own email account.

   Also, in web.config file, in "ERROR REPORTING" section, the 'ErrorFromEmail' and 'ErrorToEmail' values are set to **youremail@company.domain'**. Use a valid Administrator email address to replace **'youremail@company.domain'** value in these 2 configurations.

```
<!--
  Email system setup.
  EmailServerType key is the server type - set to "gmail" or "custom".
  EmailServer key is the server name of the email server i.e. gmail/yahoo/homail or some corporate email server
  EmailUsername key is the username for logging into the email server.
  EmailUserpassword key is the password for the user that is logging into the email server.
  EmailPort key is the email server port.
  EmailEnableSSL key is to set SSL communication true or false
-->

<!-- In case of corporate exchange server, the setting will be as below. -->
<!--
  <add key="EmailServerType" value="custom"/>
  <add key="EmailServer" value="Your Corporate EMAIL Server/>
  <add key="EmailUsername" value=""/>
  <add key="EmailUserpassword" value=""/>
-->

<!-- In case of third party hosted exchange server for small businesses, the setting will be as below. -->
<!--
  <add key="EmailServerType" value="gmail"/>
  <add key="EmailServer" value="Your Company SMTP Server OR Gmail/Yahoo email SMTP Server/>
  <add key="EmailUsername" value="youremail@company.domain"/>
  <add key="EmailUserpassword" value="youremailpassword"/>
  <add key="EmailPort" value="yourEmailServerPort"/>
  <add key="EmailEnableSSL" value="false"/>
-->

<!-- Default Settings: In case of gmail mail server, the setting will be as below. -->
<add key="EmailServerType" value="gmail"/>
<add key="EmailServer" value="smtp.gmail.com"/>
<add key="EmailUsername" value="pocabits@gmail.com"/>
<add key="EmailUserpassword" value="Poc@123456789"/>
<add key="EmailPort" value="587"/>
<add key="EmailEnableSSL" value="true"/>
```

```
  <!-- ERROR REPORTING -->
  <!-- ONLY ONE FROM AND TO EMAIL ALLOWED-->
  <add key="SendErrorEmail" value="true"/>
  <add key="CreateErrorLog" value="true"/>
  <add key="ForceErrorMessage" value="0"/>
  <add key="ErrorFromEmail" value="youremail@domain.com"/>
  <add key="ErrorToEmail" value="youremail@domain.com"/>
```

7. Open the URL http://poca.pub.com/ and Log into the application with the User ID “Admin” and password “pocaadmin$”

5. ADDITIONAL NOTES:

- The POCA Installation directory also contains the folder “Poca_Source_Code” that contains the source codes for not only the main POCA application but for all of its dependent projects. If you wish to update these code sets then you can just copy this folder to your development system and open the “WebApp.sln” file in Visual Studio 2010. Please note that FDA will not provide any help or technical support to understand the source code.
- How do I fix the ORA-65096 error?: **(ONLY FOR oracle 12c Container database)**
  In Oracle 12c database, while running the script, create_poca.sql, you may get errors ORA-65096: Invalid common user or role name. If the database is created as a **container database**, the user cannot be created and we receive “ORA-65096: Invalid common user or role name in Oracle” error.
  There are two options to fix tis error

  a. connect system/manager as sysdba

     SQl> alter session set "_ORACLE_SCRIPT"=true;

  b. Add the c## prefix to the username poca as c##poca in the script create_poca.sql and run the script. Also add c## prefix as c##poca in poca_import.bat batch file before running the batch file.